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Ricketts, David

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**DIAGNOSIS OF OCCLUSAL CARIES BY
ELECTRICAL RESISTANCE MEASUREMENTS.**

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A thesis submitted for the degree of

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ABSTRACT.

Occlusal caries is difficult to diagnose accurately. Electronic caries diagnosis, a technique based upon the decreased resistance of carious tooth tissue, has shown promise and this thesis investigates the potential of this technique.

Initial experiments showed that resistance measurements taken *in vitro* were comparable to those *in vivo*. Subsequently a number of investigations were conducted *in vitro*. Resistance readings were correlated with both lesion depth and mineral content, using a prototype electronic caries meter (ECM) and a new histological validating technique (microfocal radiography). Results showed mineral loss in enamel may be more relevant to resistance measurements than lesion depth. A number of variables that could affect the accuracy and reproducibility of readings were investigated. The critical variables were shown to be airflow, essential to prevent surface conduction in saliva, and the timing of resistance readings. Electronic diagnosis was compared with more conventional methods such as vision, use of radiographs and fibre optic transillumination. Use of 5 examiners enabled inter- and intra-examiner reproducibility to be checked with each diagnostic system. The electronic caries meters investigated were found to be more sensitive and reproducible in the diagnosis of occlusal demineralisation in enamel than other conventional examination techniques.

Finally, a clinical study was undertaken on 82 teeth deemed to require an occlusal restoration to correlate the visual, radiographic and electronic diagnosis of occlusal caries with dentine demineralisation assessed during cavity preparation. Microbiological

sampling of dentine was used to verify the level of infection of the demineralised dentine. Results showed the ECM predicts reliably early dentine demineralisation but the demineralised dentine is not necessarily infected. Thus the value of electronic caries diagnosis may be to monitor early lesion progression or arrest. This should allow a practitioner to diagnose caries risk and thus target preventive measures, such as fissure sealing, at an appropriate population.

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CHAPTER 1: LITERATURE REVIEW.

1.1 Introduction: The relevance of caries diagnosis.

The diagnosis of caries is an integral part of dentistry used by both clinicians and epidemiologists. The clinician makes diagnoses so that care can be planned for individual patients. The epidemiologist makes diagnoses so that cross-sectional national caries prevalence surveys can be carried out to assist with planning and the evaluation of service provision, or clinical trials of caries preventive agents can be assessed. Problems of diagnosis are now being encountered by both groups with apparent changes in the presentation of the disease and increased treatment options for its management.

This literature review, therefore, addresses the problems facing both groups of dentists and by investigating the trends in disease presentation and prevalence, attempts to explain why the diagnosis of occlusal caries is of particular importance. The development of the fissure and the resultant morphology is also reviewed, because this will in part reveal why the occlusal surface is a susceptible site for carious attack and why demineralisation in this area is difficult to diagnose. To appreciate how diagnostic tests are evaluated, the relevant statistical analyses are described prior to the review of currently accepted diagnostic tests and new techniques. Diagnosis of occlusal caries is not a simple yes/no decision, and its extrapolation to treatment is far more complicated, compounded by the number of management options. These management options are discussed in the light of current diagnostic techniques. The need for a more accurate, reproducible and objective

examination technique is then summarised in relation to the clinician and the epidemiologist.

1.1.1 The epidemiologist.

For the epidemiologist there are two common types of clinical caries study, namely epidemiological surveys and randomized clinical trials. The survey gathers one-shot, cross-sectional data and industrialized nations now conduct surveys at regular intervals (for example, in the UK they have been carried out in 1968, 1978 and 1988 for adults, and in 1973, 1983 and 1993 for children). This permits analysis of disease trends in the population which is essential information for judging shifts in disease patterns and the efficacy of existing oral health care systems, as well as for planning and evaluating public health measures. Clinical trials, on the other hand, are designed to evaluate the effectiveness of a particular therapy. In these, it is important to follow the changes that occur in experimental and control groups over a period of time, often as short as a few years. Such studies depend on measurement of the incidence of caries; a toothpaste trial is an obvious example. The criteria employed by the epidemiologist should depend upon the purpose of the study, the level of precision needed to answer a particular service or research question, as well as the time and budget available.

1.1.2 The clinician.

A clinician examining an individual patient also gathers data on the prevalence and incidence of caries. On first meeting a new patient cross-sectional data is collected. There is then the potential for this data to be "updated" to longitudinal measurement at subsequent recall, provided appropriate records have been kept. However, whereas the

epidemiologist will have been trained and calibrated to apply specific diagnostic criteria reproducibly, the clinician is a more idiosyncratic animal, does not check his or her own consistency of diagnosis and some may not chart details of the condition of each tooth surface in enough detail to permit retrospective assessments to be made.

It is of interest to compare the use made of the data gathered by the two groups. The epidemiologist in a National Survey setting is producing data for use by those in Dental Public Health, by service managers and by politicians. Thus, at an individual subject level, it may not matter whether every diagnosis is correct, provided the overall picture represents a valid pattern of disease trends. For the clinician, however, diagnosis will trigger a treatment decision which may, depending upon the presence of caries and its extent, involve operative intervention, a decision to treat preventively or a diagnosis of health where no treatment is required.

The modern clinician's aim should be to diagnose caries before cavitation has occurred so that preventive treatment may arrest it. To this end the clinician should examine clean, dry, well-lit teeth and use bitewing radiographs (Kidd, 1984). In contrast the survey epidemiologist, as described in Adult Dental Health report (Todd and Lader, 1991), examines wet teeth, illuminated by a headlamp. The teeth have not been specifically cleaned prior to examination and no radiographs are available. The objective here is to diagnose caries visually at the level of cavitation into dentine. Although there is some debate as to the precise interpretation of the written criteria which were utilised, the criteria stated that where doubt exists the surface is marked as sound unless the point of the blunt probe supplied (diam. 0.7mm) enters the lesion. The philosophy behind this

diagnostic threshold was that the early lesion cannot readily be diagnosed in a field setting by multiple examiners and the cavitation stage is one that calls unequivocally for a restoration (Downer and O'Mullane, 1975). It should be noted, however, that even in an era when recommendations are against restoring small lesions many practitioners still claim to restore lesions prior to physical cavitation (Nuttall and Pitts, 1990). The field of predicting what treatment will be provided using the results of epidemiological surveys is a complex one which should not be oversimplified (Nuttall, 1983; Nuttall and Davies, 1988). In addition to its link with treatment provision, the cavitation level of diagnosis may be (or has been) a practical necessity to achieve reproducibility, bearing in mind the constraints of the examining conditions.

However, it is possible that this diagnostic threshold is not sufficiently in tune with modern concepts of clinical management to provide the data that politicians and health service planners need. The modern practitioner would aim to intervene with preventive treatment before a filling is needed and this management also has cost and manpower implications. In addition the cavitation level of diagnosis may no longer be applicable in many western countries following a change in the presentation of the disease. In response to these changes the British Association for the Study of Community Dentistry (BASCD) has recently clarified the interpretation of its criteria for both child and adult epidemiological surveys. These are now entirely visual and record caries into dentine whether or not clinical cavitation is evident (Pitts, 1993). Although the criteria should be maintained as compatible with their predecessors when trends in disease prevalence over time are to be monitored, maintaining exactly the same criteria in the face of changes in the presentation of the disease will not provide valid estimates of trends. It

is interesting to note that the new BASCD criteria are now in line with Dutch survey methods (Kalsbeek *et al.*, 1991) although in Holland the examinations have the advantage of taking place in a dental chair, illuminated by a normal dental light, and in some bitewing radiographs were also taken (Kalsbeek *et al.*, 1993).

1.1.3 Occlusal caries diagnosis.

A review of epidemiological surveys carried out between 1954 and 1981 (Stamm, 1984) has shown an unequivocal reduction in caries experience of children aged 8-15 years. Whilst the reduction in smooth surface caries has been considerable, that of occlusal caries has been less marked (Anderson *et al.*, 1982). As a result, studies have shown that occlusal caries now accounts for the majority of lesions (Anderson *et al.*, 1982; König, 1982; Ripa *et al.*, 1985 & 1988; Dummer *et al.*, 1990; Pitts and Davies, 1992). However, it has been brought to the attention of the profession in the United Kingdom by clinicians writing letters to the British Dental Journal (Stean, 1982; Vellender, 1982; Usher, 1982; Millman, 1984) that occlusal caries appears to have become more difficult to diagnose in recent years. It was suggested that fluoride encourages remineralisation of the enamel lesion, which, in those cases where net progression continued, masked extensive destruction of the underlying dentine from visual examination. The importance of a careful examination of radiographs was mentioned by practitioners as an aid to diagnosis (Stean, 1982; Usher, 1982; Millman, 1984). This apparent phenomenon of what has been termed "occult caries" or "fluoride caries" is not however new; Hyatt in 1931 described "how deeply decay may progress at the base of a pit or fissure without giving any external evidence of its presence".

1.2 Fissure development, morphology and caries.

1.2.1 Fissure development.

To understand the problems of occlusal caries diagnosis the tooth's development and morphology must be appreciated. The ultimate occlusal morphology is established at the bell stage of tooth development. Initially, growth of the internal enamel epithelium (IEE) causes it to fold, establishing the shape of the presumptive enamel dentine junction (EDJ).

The laying down of dentine and then enamel is initiated in the region of the cuspal elevations and as this occurs the definitive shape of the EDJ takes form. Cells of the IEE between the developing cusps, continue to divide making it buckle into the dental papilla. Dentine and enamel formation now ensues along and down into the now invaginated IEE (Osborn and ten Cate, 1976). Enamel forms on the walls of the invagination as the ameloblasts retreat from what is now the EDJ. As the ameloblasts from opposing walls approximate to one another, constriction of the blood vessels supplying them can occur. As a result the enamel may be thin at the base of a fissure or even absent, resulting in "exposed" dentine (Boyde, 1989). It has been calculated that the mean enamel thickness from the base of the fissure to the enamel dentine junction is 0.2mm (range 0.05mm - 0.5mm) for premolars and 0.33mm (range 0mm - 0.8mm) for molars (Rohr *et al.*, 1991). Boyde has even suggested that the deprived blood supply during the maturation phase results in the enamel abutting fissures reaching a lesser degree of maturity and mineralisation than found elsewhere (Boyde, 1989).

1.2.2 Gross fissure morphology.

Examination of pit and fissure morphology has in general been carried out by either producing three dimensional resin replicas, or impressions of the occlusal surface, or by serial sectioning and reconstruction. The use of a vacuum was found to be essential for the resin replica technique to ensure that the laboratory resin completely impregnated the pit and fissure system (Galil and Gwinnett, 1975 a). To this end, the additional cleaning of the teeth in sodium hypochloride with ultrasonic vibrations, has also been adopted (Juhl, 1983 a). Once the resin had set and the tooth dissolved away in hydrochloric acid, the morphology within the pits and fissures became evident. Resin replicas of unerupted premolar and molar teeth showed great diversity with many fissures and pits diverging and branching from the main fissure (Galil and Gwinnett, 1975 a). Generally premolars showed less variability with a straight or curved main fissure and three or four pits. The molars showed greater complexity with many pits arising from the main fissure. Of significance, many pits were expanded at the base or terminal portion of the replica to form a clubbed or rose head appearance (like a dental bur), producing an ideal nidus for bacterial colonisation and food impaction.

Similar work on unerupted and erupted premolars and unerupted third molars produced comparable results (Juhl, 1983 a) with the exception that lower premolars had two separate fissures and fewer pits. No difference in depth or width of pits were found between unerupted and erupted teeth and not only were the replicas of third molars more complex, but their pits were up to 50% deeper than for premolars.

Whilst resin replica studies show three-dimensional detail of the surface within the pits

and fissures, no information is provided on enamel thickness and quality. These studies should therefore be considered alongside those of sectioned teeth. Such studies have already been mentioned in section 1.2.1 on fissure development, and showed that the enamel at the base of the fissure was thinner than elsewhere. Another study of 52 caries free molars and premolars showed that all but one tooth had deeply invaginated areas extending almost to the EDJ (Gillings and Buonocore, 1961). This type of study also has disadvantages. Firstly, the section may miss the area of interest or even destroy it as up to 300 μ m tooth substance can be lost with a single section cut (Benn and Watson, 1989). In addition, it is impossible to differentiate a pit from a fissure on a single section and finally, measurements of enamel thickness depend on the orientation of the saw blade to the enamel, and hence on the obliquity of cut.

1.2.3 Fissure contents.

Ameloblasts and cells from the enamel organ have been demonstrated within the fissures of unerupted teeth (Galil and Gwinnett, 1975 b). However, on eruption the fissures soon become filled with a bacterial plaque which, under transmission electron microscopy appears to differ throughout its depth (Galil and Gwinnett, 1975 c). Near the entrance to the fissure clearly defined, well spaced bacteria (cocci, bacilli and filamentous forms) are found. In the middle region of the fissure the bacteria appear more densely packed whilst at the bottom the bacteria appear separated once again, this time by an amorphous matrix and crystalline material. Some of the bacteria themselves have shown evidence of calcification and an unsubstantiated, but plausible theory has been suggested, that such calcification in fissures may reduce their susceptibility to caries (Galil and Gwinnett, 1975 c). However, the calcification seen may be the result of an environment in which the

carious process has already arrested.

It has been well documented that caries cannot occur without oral bacteria (Orland *et al.*, 1954) and that acid production by bacteria can lead to demineralisation. Conversely there is evidence that the composition of the microflora can in turn be determined by the pH of the oral environment (Bradshaw *et al.*, 1989). The deeply invaginated fissures that encourage food stagnation also prevent the beneficial effects of saliva, such as dilution and neutralisation of plaque acid. It is therefore unlikely that the microflora associated with pit and fissure caries is comparable to that on smooth surfaces (Marsh and Martin, 1992). Additionally, microbial metabolism within the plaque will produce gradients in factors affecting the growth of other species, so producing vertical and horizontal stratification within a single fissure (Marsh and Martin, 1992).

Unfortunately, the complex anatomy of the occlusal pits and fissures hinders bacterial sampling and as such there is a lack of information in the literature on initial bacterial colonisation, stability of the flora and bacterial shifts resulting in caries development (Meirers and Schachtele, 1984). What is known, however, is that the microbial community within the fissures is less diverse than that at the approximal surface and gingival crevice. This is thought to reflect a more severe environment with a limited range of nutrients. The microflora is mainly Gram-positive and dominated by streptococci (Marsh and Martin, 1992).

1.2.4 The site of the initial occlusal carious lesion.

A number of studies have tried to relate fissure morphology with susceptibility to caries,

however, there appears to be little agreement within the literature. Some studies have found no relationship between fissure morphology and caries susceptibility (Fejerskov et al., 1973) while others have found that steep sided, narrow fissures may favour the onset of caries (König, 1963). Similarly, there is disagreement about the position of the initial lesion in relation to fissure morphology. König (1963) has reported that the base of wide fissures and the entrance and walls of narrow fissures were the site of the initial carious lesions. Juhl (1983 b) however, found no relationship between the site of lesion and fissure morphology.

Juhl (1983 b), conducted a polarised light microscopy investigation of 62 discrete lesions in extracted, serially sectioned premolars and showed that 61% of early lesions were in the enamel around the terminal end of the fissure. It has also been reported that the initial lesions in fissures may develop at independent sites along the fissure system and these independent lesions may coalesce as they enlarge (König, 1963; Mortimer, 1964). Initial lesions may also have multiple foci within sections as thin as 100 μ m, with lesions both in the upper and lower parts of the fissure (Juhl, 1983 b). This may also complicate histological validation of lesions on thin sections.

1.2.5 The timing of initial caries attack.

It has been claimed that occlusal caries peaks during eruption (Carvalho et al., 1989) and immediately after eruption (Miller and Hobson, 1956). The concept of dental caries being exclusively a disease of young, newly erupted teeth is, however, not tenable. The carious process is a potentially ubiquitous phenomenon although rates of lesion progression vary and can be modified by preventive efforts so that a clinical cavity, or a lesion visible in

dentine, may never form.

Clinical studies on caries initiation in molar teeth of American (Ripa *et al.*, 1988) and Welsh (Dummer *et al.*, 1990) children aged between 10 and 16 years appear to show that occlusal surfaces do not necessarily succumb within the first few years following eruption. In the American study first molar teeth which had been erupted for 7-10 years were still developing clinical lesions and, within the age range studied (10-16 years), the overall time that teeth were in the mouth had little effect on the vulnerability of occlusal surfaces to caries attack.

Series of longitudinal epidemiological studies of older individuals in a number of different countries have yet to be carried out to show whether this phenomenon is life-long. However, such studies will be important in order to predict the treatment needs of contemporary children as they develop through youth to middle and old age. Downer (1994) in a preliminary report of the 1993 National Survey of Childrens' Dental Health shows evidence of a further decline in caries throughout the United Kingdom compared with surveys carried out in 1973 and 1983. However, there is also evidence that the improvement seen in the caries status of UK children may now have 'bottomed out' in the 5 year olds in some areas (Pitts and Davies, 1992). Also, it is not known whether all of the current decline in caries prevalence in the young people in many areas of the developed world (Renson, 1986) is a genuine reduction in the prevalence of all stages of the carious process or whether part is merely a delay in onset and slower progression of initial lesions. Prudence and care should also be exercised in planning decisions for older groups. In older individuals with restorations there are less sound sites at risk to decay.

However, there is an increasing potential to secondary caries associated with restored surfaces and for caries on exposed root surfaces in these older adults. Caries risk factors may change adversely in older adults, more of whom are now retaining their teeth than previously (Todd and Lader, 1991).

1.3 The statistical evaluation of a diagnostic test.

Statistical evaluation of a diagnostic test is essential to assess how efficient and reproducible it will be when used clinically. It also allows comparisons to be made between different diagnostic techniques and between examiners. Once the diagnostic test has been performed, the presence or absence of disease needs to be established: the test needs to be validated.

1.3.1 Validation.

Validity by definition reflects whether a test actually measures what it is purported to measure. To evaluate a particular diagnostic technique the presence or absence of the disease needs to be confirmed, as well as the severity of disease when present. It is logical therefore that the validation technique, or "gold standard", be more accurate than the diagnostic technique. It is ideal for a procedure to be tested in the appropriate environment for which it was designed, that is the oral cavity. However, it is generally accepted that one of the most accurate assessments of a diagnostic technique for dental caries is provided by microscopic examination of histologically prepared sections (Downer, 1989). Both are possible if the examination is conducted *in vivo* and the teeth then extracted to allow histological examination (Rock and Kidd, 1988). However, this

restricts the number and type of teeth available for study because only some teeth can be extracted ethically.

For this reason many studies have been carried out in the laboratory on extracted teeth (Lussi, 1991 and 1993; Ketley and Holt, 1993; Ricketts *et al.*, 1995). These studies are convenient and therefore numerous but care must be taken to reproduce clinical variables so that the laboratory examination does indeed simulate the clinical problems. Despite the utmost care the conditions *in vivo* cannot as yet be completely reproduced. For example, in a clinical study aimed at evaluating a visual examination for occlusal caries detection, access is hindered intraorally by the soft tissues, including the tongue and vision is affected by the acquired pellicle, plaque and residues from the saliva, which may still be present in fissures despite careful cleaning. To simulate all these factors satisfactorily in a laboratory is probably impossible.

A number of histological validating techniques have been described for the examination of sections cut from extracted teeth. Polarised light microscopy (Rock and Kidd, 1988) and microradiography (Mileman and van der Weele, 1990) both demand that sections be ground to approximately 100 μ m thick. Quantification of mineral loss can be achieved with greater accuracy from the microradiographic technique, but such thin sections may miss the area of most importance or even destroy it in cutting the section. Thicker sections have been used (700 - 1000 μ m) and viewed under a stereomicroscope (Wenzel *et al.*, 1991 b) or radiographed and analysed using a measuring grid system (Penning *et al.*, 1992). Examination of simply hemisected teeth has also been used for validation of occlusal caries (Wenzel *et al.*, 1990,; Ricketts *et al.*, 1994).

Operative confirmation of caries has also been described (Verdonschot *et al.*, 1992) but ethically these tests preclude examination of teeth thought to be sound. Thus the validity of the "sound" diagnosis cannot be confirmed. Finally, some clinical studies have combined data from two or more diagnostic techniques to establish the overall number of surfaces with caries and thus established a "gold standard" (King and Shaw, 1979). King and Shaw (1979), for example, compared clinical and radiographic caries diagnosis. The number of lesions diagnosed by both methods was recorded, as well as the number of lesions diagnosed by clinical examination only and by radiographic examination only. By adding these three figures together, the total number of carious lesions was calculated and acted as the "gold standard". Such studies are fraught with problems as the presence or absence of disease cannot be truly validated.

Having obtained a "gold standard", the validity of a diagnosis can be established. Table 1.1 and the following definitions have been adapted from papers by Douglass and McNeil (1983) and Douglass (1993). Table 1.1 represents a decision matrix for the diagnosis of occlusal caries and illustrates four possible decision outcomes: true positive (TP), false positive (FP), true negative (TN) and false negative (FN). From this matrix important measures or analyses can be made: sensitivity, specificity, accuracy, likelihood ratio, positive predictive value, and negative predictive value.

Table 1.1 A fourfold classification table for occlusal caries diagnosis.

Result from validation technique	Result from diagnostic technique		TOTALS
	Sound	Cariou	
Sound	TN	FP	TN + FP
Cariou	FN	TP	FN + TP
TOTALS	TN + FN	FP + TP	

1.3.2 Sensitivity.

Sensitivity or the true positive ratio can be calculated as:

$$\text{TP} / \text{FN} + \text{TP}$$

and it measures the proportion of diseased surfaces correctly diagnosed as carious.

1.3.3 Specificity.

Specificity or the true negative ratio can be calculated as:

$$\text{TN} / \text{TN} + \text{FP}$$

and it measures the proportion of disease-free surfaces correctly identified as sound.

Both sensitivity and specificity are proportions and as such can be written as decimals or percentages.

1.3.4 Accuracy.

Accuracy is an index that measures the fraction of surfaces for which the diagnostic test is correct, that is the sum of true positive and true negative outcomes divided by all the outcomes:

$$\text{TP} + \text{TN} / \text{TN} + \text{FP} + \text{FN} + \text{TP}$$

1.3.5 Likelihood ratio.

The likelihood ratio is the true positive ratio (sensitivity) divided by the false positive ratio (or 1 - specificity). Diagnostic techniques with a high likelihood ratio are better discriminators of disease, that is they have a high sensitivity and high specificity.

1.3.6 Positive predictive value.

So far Table 1.1 has been considered in the horizontal direction and proportions calculated according to the "gold standard". These results indicate the efficiency of the diagnostic test. If Table 1.1 is analysed vertically, the probability of the diagnostic result being correct can be calculated. That is, the positive predictive value, calculated as:

$$\text{TP} / \text{FP} + \text{TP}$$

indicates the number of correct, positive disease diagnoses out of all positive disease diagnoses or the probability of the disease diagnoses being correct.

1.3.7 Negative predictive value.

Similarly, the negative predictive value is calculated thus:

$$\text{TN} / \text{TN} + \text{FN}$$

and answers the question, when the diagnostic system indicates there is no evidence of

disease, what percentage of these results are correct?

1.3.8 ROC (receiver operating characteristic) analysis.

The last decade has seen an increase in popularity of receiver (or relative) operating characteristic (ROC) curves, used in the evaluation of diagnostic techniques. The technique arose from the study of the detection and interpretation of radar signals against a background of noise. Different observers might have different thresholds for classifying a dubious image as positive, and by virtue of ROC curves each observer's response can be displayed graphically to enable a comparison of the performance of different observers (or receivers). The "operating characteristics" were defined as the variation in sensitivity and specificity with different degrees of certitude about the interpretation of an image. When the sensitivity (y-axis) and 1 minus specificity (x-axis) were plotted an ROC curve was obtained (Beck and Schultz, 1986).

An extrapolation of ROC analysis firstly to radiology and then other diagnostic techniques in dentistry was inevitable (Mileman and van der Weele, 1990; Nyttun *et al.*, 1992). The "certitude" scale used by Nyttun *et al.* (1992) for the diagnosis of either enamel or dentine caries was: almost definitely not present, probably not present, unsure, probably present and almost definitely present. The sensitivity and specificity of various diagnostic techniques were calculated at each level of certainty and an ROC curve plotted. This would appear to be the original and classic description of ROC analysis in dental caries diagnosis. However, other interpretations have been described.

When a diagnostic test produces a continuous measurement, for example the electronic

caries detector, a convenient diagnostic cut-off must be selected to calculate the sensitivity and specificity of the test for a particular event, such as dentine caries. A gaussian (normal) distribution of resistance measurements is likely to exist for both sample groups of sound and carious teeth, with some degree of overlap. Therefore, depending on the cut-off value chosen, the sensitivity and specificity will vary. Plotting the sensitivity and 1 minus specificity for all possible cut-off points results in an ROC curve (Campbell and Machin, 1990; Beck and Schultz, 1986). Thus this method of ROC curve construction is only applicable in cases where the diagnostic test results are continuously distributed.

Unfortunately in many studies discrete depth rating scales are used (Lussi, 1991; Wenzel *et al.*, 1991 b). Occlusal caries is a dynamic process of demineralisation and remineralisation. The process which predominates will dictate the outcome of the disease and this will depend on the host and environment. Diagnostic decisions made by clinicians are frequently presented as positive (carious) or negative (sound). However, in reality the decision making process is not this simple because of the continuous nature of the disease process, and the decisions made will fall in the grey area on the continuum from negative to positive (Douglass and McNeil, 1983). For this reason, various discrete levels are chosen on this continuum to differentiate subjects with and without disease. For example, in the diagnosis of occlusal caries, the levels may lie between sound, caries confined to the outer half of enamel, caries in the pulpal half of enamel, caries in the outer half of dentine and caries in the pulpal half of dentine. Sensitivity and specificity values are calculated for each cut-off level and the ROC curve generated.

It is recognised that ROC analysis on data derived from diagnostic systems which employ

discrete depth rating scales still require empirical support (Verdonschot *et al.*, 1993). Assessment of the size of occlusal lesions from radiographs involves grading them into discrete groups according to the depth, for example sound, dentine caries in outer third of dentine, middle third and pulpal third (Ricketts *et al.*, 1994). In theory, ROC analysis could have been applied to the sensitivity and specificity values calculated for each depth grading to produce an ROC curve. A preliminary investigation into the appropriateness of ROC analysis using caries depth ratings has shown that it provides valid measures of diagnostic performance which can be interpreted more clearly and unequivocally than sensitivity and specificity measurements alone (Verdonschot *et al.*, 1993). However, further work and support for this view is required.

Diagnostic techniques with high sensitivity values and high specificity values at each level will produce an ROC curve, beneath which is a proportionally large area. The greater the area, the better the technique. The maximum area possible is 1, and represents a perfect diagnostic test with no false positive results. This would be a line that started at the origin and went up the y axis to a sensitivity of 1 and then horizontally across to a false positive rate of 1 (Campbell and Machin, 1990). A diagnostic test that produces a false positive result at the same rate as true positive results would produce an ROC curve on a diagonal line $y = x$.

Sensitivity, specificity, positive predictive value and negative predictive value depend on the prevalence of disease in the study sample and the size and distribution of lesions. Inclusion of too many large lesions will result in an overestimation of sensitivity, whereas the inclusion of large numbers of sound surfaces will cause an overestimation of

specificity. ROC analysis suffers from neither of these disadvantages (Verdonschot *et al.*, 1993).

1.3.9 Reproducibility.

All of the statistical tests discussed have been based upon the assumption that the data collected has been reliable. However, dental research depends on the way a researcher interprets diagnostic criteria, and on how his or her interpretation compares with someone else's. For example epidemiological surveys conducted in two areas by two different researchers may result in two DMF values that were different. The different DMF values may either be due to a real difference in caries levels in the two areas, a result of sampling error, or due to the fact that the two examiners do not agree on what constitutes a carious lesion. Thus it is important that a diagnostic technique has an index or scale which enables examiners that use it to do so consistently with each other, that is there must be good **inter-examiner reproducibility**. Similarly it is important that a single examiner be consistent from one occasion to another. An epidemiologist re-examining subjects after a time interval will only be able to determine a real change in caries experience if he or she is consistent within themselves, that is they have good **intra-examiner reproducibility**.

Diagnostic consistency has been the subject of numerous publications and texts (Bland and Altman, 1986; Bulman and Osborn, 1989), however there appear to be no generally approved methods of measuring examiner variability. At its simplest, when using nominal scales or categories, the proportion of decisions made on two separate occasions which agree precisely can be calculated, however, this does not take into account the agreement

expected by chance. To overcome this Cohen (1960) formulated a measure, the kappa (K) statistic, which corrected for the proportion of the agreement expected by chance. The formula is:

$$K = (p_o - p_e) / (1 - p_e)$$

Where p_o is the proportion of observed agreement and p_e is the proportion of agreement which could be expected by chance. Details on how these figures are calculated are described in Bulman and Osborn (1989) and it has been suggested by Landis and Koch (1977) that a kappa value of over 0.8 indicates good agreement, over 0.6 substantial agreement and over 0.4 moderate agreement. A kappa value below 0.4 indicated only slight to fair agreement and a 0 value would indicate that the examiners made decisions as if at random.

Continuous measurements, such as electronic resistance measurements, pose a particular problem when trying to assess consistency or reproducibility. A plot of a first set of readings against a second set of readings will allow the eye to gauge the degree of agreement between the measurements. Calculation of the correlation coefficient between the two sets of readings will enable the degree of association between the readings to be assessed. A correlation coefficient above 0.7, is generally accepted as representing a strong association between the two sets of readings, however, it does not mean that the two methods agree. Perfect agreement will only be achieved if the points lie on the line of equality, $x=y$. A change in the scale of one set of measurements does not affect the correlation, but it certainly affects the agreement. The intraclass correlation coefficient has been designed to overcome this anomaly (Bravo and Potvin, 1991) and is derived from an ANOVA table. The statistical background to the intraclass correlation is complex

and will not be discussed further.

To overcome the potential pitfalls described above, Bland and Altman (1986) have described an alternative method of assessing the consistency of continuous measurements, by calculation of the "limits of agreement" between repeated readings. In this analysis, the mean value of each pair of readings is calculated together with the difference between them; the difference is then plotted against the mean, so that the distribution of the disagreement can be subjectively assessed. The mean of the differences (d) is then calculated together with the standard deviation (SD). The "limits of agreement" (or more accurately the 95% confidence limits) between which 95% of the repeated readings will lie are then represented by $d-2SD$ and $d+2SD$ (or more precisely $d-1.96SD$ and $d+1.96SD$). For acceptable reproducibility, the limits of agreement should represent a low percentage of the actual size of the readings being measured.

1.4 Diagnostic methods for occlusal caries detection.

This section of the literature review re-evaluates the accuracy of currently accepted examination techniques. It also addresses how, using existing technology, these techniques can be improved or enhanced and what advances are being made with relatively new innovations.

1.4.1 Visual examination.

The earliest, clinically visible, manifestation of dental caries is the white spot lesion and

to detect this reliably teeth should be clean and dry. Plaque and pools and bubbles of saliva can obscure small cavities, let alone white spots. In addition, the white spot is more obvious when teeth are dry because of the different refractive indices of enamel, water and air (Thylstrup and Fejerskov, 1994). The refractive index of enamel is 1.62. When demineralized, enamel becomes porous: if the teeth are wet these pores are filled with a watery medium having a refractive index of 1.33, and when the porosity is considerable this difference in refractive index will cause the tissue to lose its translucency and appear opaque. If the enamel is now dried the water is replaced with air of refractive index 1.0, the difference in refractive index between the air and the enamel is greater than between water and enamel and so the lesion is now more obvious. Consequently, less advanced lesions can be detected.

White spot lesions can be seen around the opening of an occlusal fissure. The white spot lesions may have a mat or dull appearance and this has been taken to indicate active disease (Carvalho *et al.*, 1989). Alternatively, fissures may be stained and this appearance may (or may not) indicate a carious lesion (König, 1966; Marthaler *et al.*, 1990). The area of enamel around the fissure may also appear opaque, or have a greyish tinge indicative of stained dentine caries shining up through the overlying enamel.

Unfortunately, however, the lesion may be hidden on the walls of the fissure (Juhl, 1983 b) and not be visible clinically. From this stage the lesion may advance along the enamel prisms towards the enamel-dentine junction on all sides of the fissure. The overall appearance of a lesion of this extent is that of a cone, but, unlike the smooth surface lesion, the base of the cone is at the enamel-dentine junction. Thus although a fissure

may appear healthy, extensive caries may still be present underneath it.

All the appearances described thus far might be scored as sound fissures by the epidemiologist who only recognises caries at the level of the occlusal cavity in the United Kingdom National Survey. In other situations, such as clinical trials and specific caries studies, more sensitive diagnostic thresholds may be used which will detect higher overall prevalences of disease (Pitts and Fyffe, 1988; Ismail *et al.*, 1992). The traditional survey epidemiologist working at the cavitation level is unlikely to make false positive diagnoses; however, caries will be missed. A recent epidemiological study carried out in Holland, where bitewing radiographs were available to supplement clinical examination, showed that in 20 year olds 50% of visually sound occlusal surfaces had a radiolucency in dentine on bitewing radiographs (Weerheijm *et al.*, 1992 a). Such lesions are likely to involve considerable demineralization of the dentine since the X-rays pass through intact buccal and lingual enamel which will be superimposed on the radiographic image of the demineralized dentine.

The problem of under-diagnosis of occlusal dentine caries from a clinical examination alone has been highlighted by four laboratory studies where dentists' diagnoses were verified using a histological examination as the "gold standard" (Kay *et al.*, 1988; Wenzel *et al.*, 1991 b; Ketley and Holt, 1993; Ricketts *et al.*, 1995). These studies are not directly applicable to the clinical situation, since it is easier to see teeth clearly under laboratory conditions. They showed that, even with such ideal visual examining conditions, dentists only detect between 20% and 48% of lesions penetrating to dentine, the remainder being missed.

1.4.2 Techniques to enhance visual diagnosis.

The technique of transillumination is adopted by most practitioners in the diagnosis of anterior approximal caries where the lip is used to shadow the tooth and the mirror to reflect the light. This technique was used by Dominkovic (1975), in the diagnosis of occlusal caries. An extension of this technique is fiberoptic transillumination (FOTI) which makes use of the fact that caries has a lower index of light transmission than sound tooth structure and as such shows up as a dark shadow. The only clinical and laboratory study where histological examination was the "gold standard" confirming the presence or absence of demineralization, showed FOTI to be of no assistance in detecting occlusal enamel lesions (Rock and Kidd, 1988). Subsequently a laboratory study showed that occlusal caries in dentine could be diagnosed more accurately by FOTI than by radiograph (Wenzel *et al.*, 1992). Recent work from Holland, where operative intervention was the "gold standard" (Verdonschot *et al.*, 1992) showed that FOTI would often miss occlusal caries (low sensitivity) but when FOTI predicted caries, demineralization was usually present (high predictive value positive).

Recently, the possibility of using endoscopes for caries diagnosis has been investigated (Longbottom and Pitts, 1990). Endoscopes are comparable to periscopes and enable the operator to see around corners. They are based on bundles of optical fibres, combined with lenses and mirrors, which can relay images to an attached viewer and allow a magnified image to be seen. The technique has now been developed to incorporate a miniature video camera (Pitts and Longbottom, 1991) which will allow storage and retrieval of data in much the same way as a bitewing radiograph. Retrieval of visual data had previously been attempted from photographs (Dooland and Smales, 1982; Weerheijm

et al., 1989) but while one study claimed the flash photograph revealed more information about carious occlusal surfaces (Weerheijm *et al.*, 1989) the other found the method inadequate (Dooland and Smales, 1982). The diagnostic capability of the endoscope and video camera has recently been assessed in the laboratory using histological examination as the validating criterion (Pitts and Longbottom, 1991). It appears that the technique has potential for recognizing small lesions, especially those confined to enamel (Longbottom, PhD thesis, 1992) because it is both sensitive (it will recognise disease) and specific (it will recognise health). This seems an important advance with potential for use both by the clinician and the epidemiologist and further evaluation is needed.

Luminescence from human teeth illuminated by an argon-ion laser (wavelength 488 nm) has also been observed and photographed in the laboratory (Bjelkhagen *et al.*, 1982) and offers another promising research possibility. Although safety factors were claimed not to be a problem in clinical use, cost might make commercial development unrealistic. Fluorescence of tooth enamel may be excited with conventional blue dental curing lights. When this image is viewed through a specific optical filter (with or without the use of an endoscope) caries diagnosis is facilitated (Longbottom and Pitts, 1990).

1.4.3 Probing.

The time-honoured method of detecting occlusal caries is the use of a sharp probe. GV Black (1936) described the technique thus:

"The point should be applied with some pressure and if it enters the enamel a little, so that a very slight pull is required to remove it, the pit should be marked for restoration, even though there is no sign of decay."

Today there is some controversy on whether probes should be used for caries diagnosis. American epidemiologists still favour their use (Newbrun, 1993) but European workers claim that probing is destructive, producing irreversible traumatic defects in demineralized areas (Ekstrand *et al.*, 1987) and a subsequent increased rate of further demineralisation (van Dorp *et al.*, 1988). In addition, the diagnosis is not accurate. Stickiness may reflect the morphology of the fissure or the pressure exerted on the probe rather than caries (Parfitt, 1954; Miller and Hobson, 1956). Recent laboratory work has shown the majority of sticky fissures to be carious but caries in dentine was frequently missed by this tactile diagnostic method (Lussi, 1991; Penning *et al.*, 1992), which did not improve the diagnostic capability of a purely visual examination (Lussi, 1991).

1.4.4 Radiography.

Any discussion of the use of radiography for diagnosis must be accompanied by a consideration of the risks attached to the use of ionizing radiation. The guiding principle should be that benefits should be weighed against risks and that all unnecessary exposure to radiation should be eliminated (for review of some issues see Pitts and Kidd, 1992). It follows therefore that radiographs should not be used for purely epidemiological (survey) data unless such films are also clinically justified and available to clinicians who are caring for the individuals concerned. This does not preclude the use of radiographs in surveys, but may mean that some surveys are carried out in a dental practice where the patient will subsequently be treated or at other locations in collaboration with general dentists.

Scientific study over many years has confirmed the importance of the bitewing radiograph in the diagnosis of approximal caries (Kidd and Pitts, 1990). The radiograph is particularly important in the diagnosis of the initial approximal lesion which is radiologically confined to enamel. The situation with occlusal caries is rather different, however. Superimposition of buccal and lingual enamel on the fissure system appears to make diagnosis of the enamel lesion impossible clinically although some laboratory studies, one of which did not apparently simulate superimposition of soft tissues, claim some occlusal enamel lesions can be seen on the radiograph (Russell and Pitts, 1993 a; Tveit *et al.*, 1991). Clinicians report that carious lesions visible in dentine on bitewing radiographs are large when treated operatively. Thus the radiograph appears to be more of a safety net than an accurate diagnostic tool for this type of lesion.

Despite this, two recent laboratory studies have shown that clinicians diagnose occlusal caries in the middle third of dentine more reliably from a bitewing radiograph than from a visual, clinical examination alone (Ketley and Holt, 1993; Ricketts, 1995). This may be more of a reflection of the inadequacy of the clinical examination than praise of the radiograph as a diagnostic tool, but since another laboratory study showed visual diagnosis in optimal *in vitro* conditions to be more sensitive than radiographic diagnosis (Russell and Pitts, 1991) further work must be done. Such laboratory studies have the advantage that histology or operative caries removal can be used as the "gold standard" to verify the radiographic diagnosis (Tveit *et al.*, 1991; Ricketts *et al.*, 1995), a luxury not available to clinicians or epidemiologists in surveys or clinical trials. Such studies can show how many "false positives" the radiographs produce, a false positive being an over-estimation of the disease present. All the laboratory studies show that false positives occur but are

not common or, to put it another way, the specificity of the technique is high (Russell and Pitts, 1991; Tveit *et al.*, 1991; Ricketts *et al.*, 1995). There may, however, be a change in the impact of false positives as caries prevalence declines (Downer, 1992; Wenzel *et al.*, 1993). The overall specificity values for occlusal caries are, however, reassuring for the clinician because it implies that operative treatment will rarely be done unnecessarily as a result of the radiographic examination. On the other hand, radiographs have been shown to underestimate lesion size considerably (van Amerongen *et al.*, 1992; Ricketts, *et al.*, 1994). The clinical relevance of this is that lesions may be much larger than they appear radiographically. Dentine caries on radiograph should trigger operative treatment, but radiographs should not be relied upon to monitor disease progression or arrest on occlusal surfaces.

When, in the early 1980s, practitioners first alerted the profession in the UK to the problems of occlusal caries diagnosis and advised their colleagues to examine radiographs carefully (Stean, 1982; Usher, 1982; Millman, 1984) there was little scientific evidence to support this issue. Studies published in 1979 (King and Shaw, 1979) and 1982 (Dooland and Smales, 1982) which compared clinical and radiographic diagnosis in the 1970s showed that radiographs would add little to a clinical examination in a clinical trial at that time.

Since then, careful scientific evaluation appears not only to support the practitioners' suggestion that radiographs are important, but to show that the radiograph will disclose more occlusal caries than a clinical examination. Although no studies appear to have been carried out on adults, six clinical studies on children have used a similar methodology

examining radiographically fissures denoted as sound clinically (Allan and Naylor, 1984; Sawle and Andlaw, 1988; Creanor *et al.*, 1990; Kidd *et al.*, 1992; Weerheijm *et al.*, 1992 a, b). Unfortunately the clinical diagnostic threshold of what constituted caries was not the same in all studies. For instance in some studies only a cavity was recorded as caries (Kidd *et al.*, 1992) whereas in others, stained fissures and the greyish tinge of enamel undermined by caries were also included as caries clinically (Creanor *et al.*, 1990; Weerheijm *et al.*, 1992 a). Although differences in caries prevalence, sample selection and treatment histories, means that the studies cannot be directly compared, some important new information has emerged. The percentage of clinically sound teeth with occlusal dentine caries on radiograph varies greatly from 1.4% (Creanor *et al.*, 1990) to 50% (Weerheijm *et al.*, 1992 a) depending on diagnostic criteria, subject's age and the arch, upper or lower. In some studies the radiograph was more important in lower molars than upper molars (Creanor *et al.*, 1990; Sawle and Andlaw, 1991; Kidd *et al.*, 1992). There is some evidence that occlusal caries was more difficult to diagnose clinically in 1982 than in 1974 (Sawle and Andlaw, 1988). One study shows that when 14 and 20 year olds are compared, the older the subject, the more important the radiograph (Weerheijm *et al.*, 1992 a). In this same study a significant number of occlusal radiolucencies were noted in fissure sealed teeth. Where the caries diagnostic threshold used was at the cavitation level, the radiograph was found to be of particular importance (Creanor *et al.*, 1990; Weerheijm *et al.*, 1992 a) because a number of teeth that would have been scored as sound by this criteria showed extensive dentine caries. Of particular relevance is a study of children (mean age 12.4 years, SD 2.7) where 15% of completely sound occlusal caries showed obvious lesions in dentine on bitewing (Weerheijm *et al.*, 1992 (b)).



It must be remembered that in all these clinical studies there is no operative, or histological, "gold standard". For this reason the number of false positive diagnoses on radiograph is unknown. A large clinical trial where operative intervention is used as a validating criterion seems indicated. Such a trial would allow the calculation of the appropriate factors which would be needed to convert current "clinical examination alone" survey data at the caries into dentine diagnostic threshold into "clinical plus radiographic examination" with the 1990s pattern of caries attack. This would be useful as recent work with regularly attending Scottish 12 year olds demonstrates that there are likely to be large differences in the estimations of caries prevalence made by epidemiologists and practitioners (Pitts *et al.*, 1993). These correction factors, appropriate for different age groups and caries levels, might show the treatment that general practitioners might provide for these populations. However, while these types of study would show the number of false positive diagnoses made from radiograph, they would not show false negatives since these would never be treated operatively.

Finally, a number of laboratory studies have attempted to enhance radiographic diagnosis (Wenzel *et al.*, 1990; Wenzel *et al.*, 1991 b; Wenzel and Fejerskov, 1992; Ricketts *et al.*, 1994). Digital image processing to enhance the edges of the lesion, xeroradiographs and over-exposed bitewing radiographs all reveal more occlusal caries than conventional films but more false positive diagnoses are made and thus these techniques cannot be recommended. The Wenzel and Fejerskov study (1992) was of particular interest because radiographs were taken *in vivo* before extraction of third molars. The authors noted that 50% of the radiographs were deemed too light for optimal reading by the radiologist. This may partly explain why radiographic accuracy increased to such a large extent after digital

contrast enhancement. The potential of radiovisiography in caries diagnosis is also being investigated (Russell and Pitts, 1991; Wenzel *et al.*, 1991 a; Russell and Pitts, 1993 a and b). The latter is an interesting possibility because the radiation dose is reduced. It appears that a staircase of improvement is available by electronically reprocessing the stored low-dose image.

1.4.5 Ultra-sonic detection.

Access to the lesion is a basic problem in fissure caries diagnosis and in medicine organs inaccessible to direct viewing are imaged using ultra-sound. The technique has been used on artificial lesions in the laboratory (Ng *et al.*; 1988) and a prototype has been produced for clinical evaluation (Cowan, 1991). However, the irregularities found in pits and fissures and high surface reflection may preclude its use in this region.

1.4.6 Electronic caries detection.

The search for a method by which the formation and progress of very early demineralization in the fissure may be monitored has led to the development of the electronic caries detector. This technique is dependent on the microscopic structure of dentine and enamel, and basic principles of electronics.

1.4.6.1 Microscopic structure of dentine and enamel.

The fissure, filled with a concoction of bacteria, associated by-products and food particles, is kept hydrated with water and ions from the saliva and tissue fluids from the pulp. Although the contribution made by the latter seems unlikely, it must be borne in mind that even sound dentine and enamel are porous.

Mature human dentine is composed of inorganic material (70% by weight), organic material which is mostly collagen (20% by weight) and water (10% by weight). Dentinal tubules, 2-5 μ m in diameter, radiate from the pulp to the enamel dentine junction (EDJ) and many finer lateral tubules (0.2 μ m) allow communication between them. In cross section, it has been reported that the tubules can account for 22.1% of the total cross sectional area on the pulpal side of the dentine and 1% at the EDJ (Pashley *et al.*, 1978). The variation can be explained by the fact that as the tubules pass from the pulp to the EDJ they diverge and become narrower. It is therefore of little surprise that rapid fluid movement through dentine has been well documented (Osborn and ten Cate, 1976; Pashley *et al.*, 1978; Pashley *et al.*, 1987).

The structure of enamel is markedly different; it's inorganic element (hydroxyapatite) contributes approximately 95% by weight, with 1% by weight of organic materials and 4% by weight of water. By volume, the water and organic matrix may constitute up to 15% of the enamel compared to 53% (32% organic and 21% water) for dentine. Viewed with the light microscope, the enamel is seen to be made up of prisms approximately 3-6 μ m in diameter, surrounded by a prism sheath. Pore sizes in enamel have been investigated using water sorption techniques and found to have radii in the order of 2-6nm (Moreno and Zahradnik, 1973; Dibden and Poole, 1982). A frequency distribution of pore volume demonstrates a bimodal distribution with pore radii of either 2.3nm or 5.8nm. This feature, of pores with two different sizes, possibly relates to inter-prismatic and intra-prismatic spaces. Microscopic examination following dye stain permeability studies, show that the main channels for diffusion are the inter-prismatic substance, tufts and lamellae (Fish, 1933).

Therefore, despite the dense structure of sound enamel, it too is permeable to water and ions (Jenkins, 1978), albeit to a much lesser degree than dentine. Estimation of enamel permeability by electrochemical means has been described (Scholberg *et al.*, 1984) and is the foundation of electronic caries detection. Sound enamel is not a good electric conductor, the pore volume being very small, but demineralisation which occurs during the carious process, creates microscopic cavities which join to form conductive pathways. Pincus in 1951 was the first to identify the potential of such measurements and the method was developed in two centres, a world apart; Tufts University, Boston, USA (White *et al.*, 1978) and Tokyo, Japan (Sawada *et al.*, 1986). Two machines were produced commercially called the Vanguard Electronic Caries Detector (Massachusetts Manufacturing Corporation, Cambridge, Massachusetts) and the Caries Meter L (G-C International Corp. Interleuvenlaan, Leuven) but neither are produced today.

1.4.6.2 Electronic measurements.

This thesis addresses the clinical applications of electronic caries meters in the diagnosis of occlusal caries. The complex physics that relates to such measurements is not dealt with, but in its simplest form, the resistance of a circuit (R) is the ratio of the potential difference (V) across its ends to the current (I) passing through it. That is:

$$R = V/I$$

This is Ohm's law and applies to direct current (dc.) circuits. However, when a constant potential difference is applied to a conductivity cell, time dependent changes such as polarisation will occur. Consider an electrolytic solution containing ions and a pair of parallel electrodes with an area A separated by a distance L . If a constant potential difference is applied across the cell at a constant temperature, mobile charges will migrate

to the electrodes of the opposite charge. However, there will be no transfer of charge across the interface and so polarisation occurs (Levinkind, 1992). The two commercial caries detector machines overcame this potential problem by employing an alternating (ac.) voltage (Vanguard 25 Hz, Caries Meter L 400 Hz).

When a sinusoidally alternating current is applied across a purely resistive circuit, the current that is produced is sinusoidally in phase with the voltage and Ohm's law still applies. However, once changing voltages and currents are encountered, circuit elements such as capacitors, which are functionless in dc. circuits, become important. Unlike a resistor, which has resistance, a capacitor has reactance. Reactance (R_c) can be calculated using the formulae:

$$R_c = 1/\omega C \quad \text{where } \omega = 2\pi f$$

and f is the frequency and C the capacitance. Thus a capacitor behaves like a frequency-dependent resistor. A pure capacitor, will also lead to a phase shift of the current produced (phase shifted component) of 90° .

When electrical measurements across teeth are concerned, neither pure resistors nor pure capacitors (as described above) are encountered, a complex combination of components results. Indeed studies have been carried out to produce circuits which model the impedance characteristics of unerupted permanent human, deciduous human and bovine enamel (Levinkind *et al.*, 1990). It is now possible to generalise Ohm's law, replacing the term resistance with impedance, in order to describe any alternating circuit containing these devices (ie. resistors and capacitors). The total impedance is equal to the sum of the resistance and reactance.

A combination of resistors and capacitors not only affects the amplitude of the output of a circuit, but also results in frequency dependent changes in the amount of phase shift experienced (due to the capacitance effect). Connected as in Figure 1.1 it is found that at low frequencies the phase shift is negligible and the output looks like that of a pure resistor (Horowitz and Hill, 1980; Borsboom and Boer, personal communication).

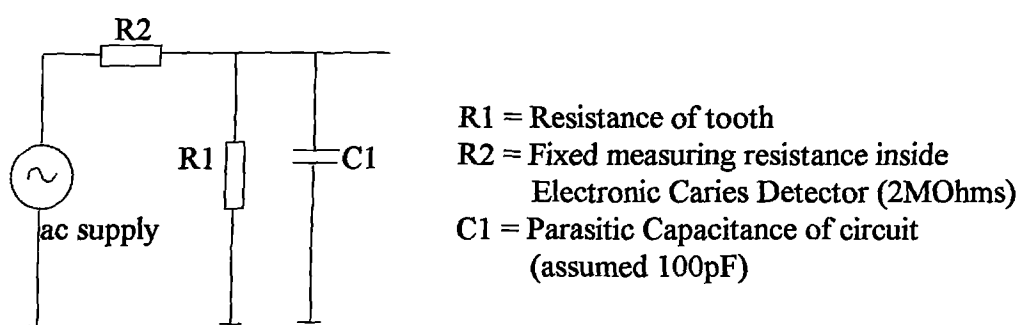


Figure 1.1 Combination of resistors and capacitors used in electronic caries detectors which for low frequency ac. currents leads to a negligible phase shift (information supplied by Borsboom and de Boer, 1994).

In reality, there will always be reactance where alternating currents are concerned and true resistance can only be calculated by measuring the impedance at different frequencies and using complex mathematics to determine the resistance at 0Hz (Hoppenbrouwers *et al.*, 1986). However, the term resistance is conceptually more acceptable to the lay-man and will be used in this thesis in conjunction with machines operating at low frequencies. This is true of the Vanguard which operates at a frequency of 25Hz.

1.4.6.3. Resistance and resistivity.

Resistivity is the property by which materials can be compared. A conductor of length L , cross sectional area A , and resistance R between its ends will have a resistivity of σ given by the formula:

$$\sigma = RA/L$$

Resistivity can be calculated in the laboratory by measuring the resistance of enamel or dentine samples of known dimension, and its units can be recorded as Ωcm . Mumford (1967) found that the resistivity of dentine, measured along the lines of the dentinal tubules, was 11×10^3 to $52 \times 10^3 \Omega\text{cm}$ (mean = $33 \times 10^3 \Omega\text{cm}$) and that of enamel was 2.6×10^6 to $6.9 \times 10^6 \Omega\text{cm}$ (mean = $4.5 \times 10^6 \Omega\text{cm}$). However, a direct current was used and despite attempts to reduce the effects of polarisation, they can not be completely ignored and will lead to an elevation of true values of electrical resistance. Despite this potential problem, Mumford (1967) claimed comparable results to that of a similar study by Björn in 1946 for both enamel and dentine.

A more recent and complex study measured the electrical impedance of enamel at various frequencies and used complex non-linear regression analysis algorithm to determine the resistance at 0Hz (Hoppenbrouwers *et al.*, 1986). The results obtained for full thickness buccal and lingual enamel were 0.68×10^6 to $21.1 \times 10^6 \Omega\text{cm}$ (recorded as 680 k Ωcm and 21100 k Ωcm).

Various factors have been shown to affect the electrical properties of both sound dentine and enamel. Studies determining such factors have analysed sections of each material.

Section preparation will inevitably result in a smear layer and for dentine, tubular occlusion. The smear layer itself can account for up to 20% of the total resistance of a section of dentine (Levinkind *et al.*, 1992). With the smear layer removed, regional variations occur, sections cut parallel to the occlusal surface and closer to the EDJ have higher resistance values than those nearer the pulp. These findings can be explained by the difference in the sum of the cross-sectional areas of the tubules and hence conductive pathways. Similarly, large regional variation in dentine permeability has been shown to exist across a single section, with highest permeability over pulp horns and lowest values in the centre of the section beneath the fissure (Pashley *et al.*, 1987). This may be a function of dentine thickness, thick dentine having a higher resistance to fluid flow, compared to thinner dentine over the pulp horns (Reeder *et al.*, 1978). However, Pashley *et al.* (1987) have shown this regional variation to be an inherent property within the dentine and independent of thickness. The lower permeability of the dentine in the centre of the sections may be a result of the orientation of tubules, but if this were true increased permeability might be expected centrally than at the periphery; the tubules in the centre of the section would be cut in cross section and not obliquely as at the periphery. Although sections cut were of uniform thickness, central tubules may have a more tortuous course and longer length. The most likely explanation is that due to the invaginated occlusal surface, the central dentine is actually nearer to the EDJ than over the pulp horns.

Few studies have measured the resistance of dentine *in vivo*, due to ethical and technical difficulties. Animal models have been used and attempts made to correlate the remaining dentine thickness at the base of a cylindrical cavities with the impedance values obtained

between an electrode placed in the cavity and one on the oral mucosa (Yoshida *et al.*, 1989). The term impedance is used here as the frequency of the electronic device used was high (400Hz). Seventy eight dog teeth were investigated, and a statistically significant positive correlation was found between the remaining dentine thickness and impedance (correlation coefficients for upper and lower teeth were 0.55 ($P < 0.01$) and 0.60 ($P < 0.01$) respectively). Impedance values between 20 and 50 k Ω were recorded for cavities with remaining dentine thickness below 1mm, however, insufficient data was presented to calculate resistivity values. A large variation in the dentine thickness was observed for impedance values below 30 k Ω , which accounted for 63% of the data. The variation was attributed to a large electrical contact area, current leakage and different ages of the dogs. Alternatively it could have been due to an apparent non-standardised cavity diameter and inconsistent location, which may result in regional variations already described.

Enamel resistivity changes as a function of the distance from the EDJ, which directly reflects the change in enamel permeability. A higher resistivity (lower permeability) has been described for the surface enamel (Kambara and Konishi, 1977; Hoppenbrouwers *et al.*, 1986). Removal of successive 100 μ m-thick layers of dental enamel from the surface of an erupted tooth has shown that a surface layer (approximately 100 μ m thick) of relatively high electrical resistance exists (Hoppenbrouwers *et al.*, 1986). It was claimed by Hoppenbrouwers *et al.* (1986) that these results were in agreement with studies by Watanabe (1971) and Oiwa (1973) who found a surface layer of about 250 μ m and Ojima (1972) who found a similar layer 100 μ m thick (original papers in Japanese and not available).

Comparison of erupted and unerupted teeth showed that the resistivity of the surface of the erupted tooth was higher than for the unerupted tooth (Hoppenbrouwers *et al.*, 1986). This means that the increase in surface resistivity occurs post-eruptively and may represent post-eruptive maturation. Teeth formed and erupted in areas of water fluoridation have been shown to have enamel and dentine of higher resistance than those from non-fluoridated regions (Marci and Savini, 1967; English summary). This is a surprising result as fluorosed enamel would have been more porous. However, a study of demineralised enamel of whole teeth with an intact occlusal surface, treated with acidulated phosphate fluoride (APF), also show an increase in resistance both *in vivo* and *in vitro* (White *et al.*, 1981 a) due to remineralisation.

1.4.6.4. Electronic studies on whole teeth.

Many of the preceding studies discussed have been of carefully controlled laboratory experiments on individual tissues, which do not take into account the complex, non-standardised, composite structure of the tooth, one of the most variable aspects of which is the pit and fissure pattern. Expanding on the theory posed by Pincus (1951), Mumford (1956) demonstrated that when a probe tip was placed in the fissures of sound whole teeth and a circuit completed to an electrode within the pulp, an overall resistance of 2.6 - 20 M Ω (mean = 8.7 M Ω) was recorded. Carious sites however, gave values of 0 - 4.4 M Ω and an approximate correlation was demonstrated between resistance and depth of caries. The same publication described a pilot study *in vivo* which reflected those conclusions made in the laboratory study. Unfortunately this study used a direct current supply and as such suffered from the effects of polarisation; however, the stage was set for the development of an electronic caries detector.

Initially the Japanese led the race in the research leading to the two prototype machines. The earliest reports of an *in vivo* study gave resistance values different to those obtained by Mumford (1956), sound fissures gave values greater than 0.6 M Ω , fissures with enamel caries gave resistance values between 0.25 and 0.6 M Ω and those with dentine caries values lower than 0.25 M Ω (Mayuzumi *et al.*, 1964). The reason for the different values is unclear as inadequate information was presented in the study by Mayuzumi *et al.* (1964) about the experimental technique and circuitry employed. The only difference evident between the studies was the age of the patients. Mumford's (1956) subjects were adults whereas the Japanese study investigated 297 first molar teeth in children 7-9 years old. A significant number of these molars might not have been present intraorally for a sufficient time for post-eruptive maturation. This may explain the lower resistance value.

The American research teams first published in the 1970's and their work led to the production of the Vanguard electronic caries detector. Their research was extremely thorough and studies used histological verification to show that electrical resistance measurements were more accurate than a conventional clinical examination (White *et al.*, 1978) and that the method might have the potential to monitor disease progression (White *et al.*, 1981 b). Subsequently clinical and laboratory studies showed the ability of the machine to monitor lesion arrest and remineralization (White *et al.*, 1981 a). Laboratory (Flaitz *et al.*, 1986) and clinical studies (Rock and Kidd, 1988; Verdonschot *et al.*, 1992) have subsequently confirmed the machine's ability to diagnose the early lesion. It is both sensitive (it will detect disease) and specific (it will recognise a caries-free tooth). This machine is no longer commercially available but it appears to offer great promise in caries diagnosis and its further development is an exciting possibility. In contrast to the plethora

of research papers on the American machine, the Japanese research effort is less well publicised, being mainly in Japanese. However, this work also resulted in the development of a commercial machine called the Caries Meter L (Sawada *et al.*, 1986; Pieper *et al.*, 1990). Like the Vanguard, this machine is no longer available commercially.

1.5. Managing occlusal caries.

Having diagnosed occlusal caries, the clinician now has a wide range of therapeutic options for its management. Whereas previously the treatment decision was whether to leave a fissure untouched or place an amalgam, the dentist now has to choose between doing nothing, applying preventive agents, investigating further with an "enamel biopsy" technique (Crawford 1988), using fissure sealant preventively or therapeutically, using adhesive resin materials or an amalgam restoration (Pitts, 1992).

Assessment of caries risk is also very important so that preventive techniques can be targeted to those individuals in need. Occlusal surfaces, being the predominant site to be affected in the young, demands an examination technique accurate enough to monitor progress, arrest or remineralisation of lesions. It is ironic that the dentist needs more diagnostic information to make a logical treatment decision and assessment of caries risk just when the change in presentation of the carious process may make this diagnosis more difficult.

1.6. Summary.

1.6.1. The clinician's dilemma.

The presentation of occlusal caries appears to have changed, cavitation occurring later. Thus a careful visual examination should, wherever possible, be supplemented by bitewing radiographs although it must be appreciated that small carious lesions still cannot be diagnosed from radiographs. A sensible treatment approach, bearing in mind the diagnostic difficulty, would be "if in genuine doubt intervene with an enamel biopsy repaired with a sealant if the lesion is shallow or a sealant restoration where more extensive decay is found". It is interesting that laboratory studies seem to show that this approach is often chosen by dentists when they are asked to diagnose the extent of occlusal caries and select a treatment option (Ricketts, 1991; Lussi, 1991). Treatment decisions correlated better with histology than diagnosis of the extent of the lesion. This emphasises that there is more to a treatment decision than simple diagnosis (Kay, 1991). The need for a diagnostic technique that is more accurate than those currently available and depends less on subjective interpretation is overdue. The most promising approach for the future seems to be the development of electronic caries detection.

1.6.2. The epidemiologist's problem?

The epidemiologist conducting a large-scale National Survey type of examination seems to have a new and serious problem. Occlusal caries predominates in the young but the constraints of wet, plaque covered teeth and the absence of bitewing radiographs appear to make accurate diagnosis difficult in an era when cavitation occurs late. Can such a survey still produce reliable data to estimate disease trends and treatment needs when

disease patterns have changed and treatment options have expanded?

Even if it were possible to clean and dry teeth and reproducibly diagnose stained carious fissures as carious, the diagnosis might still underestimate the true level of disease requiring preventive and/or operative treatment. The bitewing radiograph would aid the diagnosis but could only be used ethically in a clinical setting where treatment was available. Unfortunately the few studies which include both clinical and radiographic findings are not standardized in diagnostic threshold and age of subjects and do not give similar figures for the clinical underestimation of disease. Nuttall has provided an overall factor attempting to reconcile survey findings with treatment provided but this relates to data from Scotland which is more than 10 years old (Nuttall, 1983). More recent Scottish data (Pitts *et al.*, 1993) relates only to regular child attenders and this will not be representative of findings from all population samples. Thus at present it is not possible to use the available literature to advise on a valid overall correction factor for the absence of the bitewing.

One possible way forward might be to conduct a part of future National Surveys in dental practices. Under these conditions bitewings would be ethically available and it would be practical to clean and dry teeth. In addition, electronic detection methods which show the most promise for occlusal caries diagnosis, could also be used. However, the sample examined would be limited to those who attend the dentist which could introduce bias because their disease and treatment profile may differ from the population mean. Ideally, true random samples should be examined under these conditions so that the results from this sub-set could be used to calculate overall values for the survey as a whole.

Occlusal caries now accounts for the major caries attack in children and young adults (US Public Health Service, 1981); there are now more apparently sound surfaces and less fillings (Kidd *et al.*, 1992). In the past the dentist had often made the diagnostic decision for the epidemiologist by filling the tooth, but now the examiner is confronted with more apparently sound teeth, less fillings, more sealant and more sealant restorations. Bearing in mind the conditions of examination in a National Survey, can the epidemiologist reliably distinguish a sealant restoration from a fissure sealant? How will the examiner decide whether a sealant was placed for preventive or therapeutic reasons? If the sealant was placed to prevent decay then the tooth should not be classed as decayed and filled but if the sealant was used therapeutically it should form part of the DMF index. These problems are being specifically addressed by research workers (Davies, 1991; Deery and Pitts, 1991), although to date, the studies have confirmed the problem rather than developed complete solutions. It may be that new indices are required as an adjunct to DMF.

In conclusion, it would seem wise to alert clinicians and those who plan dental services to the possibility that occlusal caries diagnosis in National Surveys may be inaccurate making prediction of disease trends, service needs and manpower requirements potentially unreliable.

1.7 General aims, research questions, and scope of studies.

The literature review has cast doubt as to the ability of clinicians and epidemiologists to diagnose occlusal caries. The potential of electronic caries detection has been suggested and provided the inspiration for this thesis, which consists of seven well defined and circumscribed studies. Different machines will be used in different studies. Initially the Vanguard electronic caries detector and the Caries Meter L will be re-evaluated (Chapter 2). Since neither of these machines are currently commercially available, subsequent studies will follow the development of a new electronic caries meter through two prototypes, the ECM I (Chapter 3) and II (Chapter 4 and 5) and will investigate different facets of diagnostic performance. Chapters 2 to 5 will address the potential of electronic caries detection for use by clinicians based upon the identification of demineralised tooth tissue. Chapter 6 will investigate the ability of various diagnostic techniques to predict infected dentine and hence the need for operative treatment. The Vanguard will be used for this study since it will span the entire 3 years of the work and is the only machine available over this time period. Finally, Chapter 7 will investigate whether a prototype ECM II, with a lower resistance scale, can be used to obtain an overall resistance reading to represent the entire occlusal surface.

The specific aims of each study are detailed in the relevant chapters but the most salient research questions addressed in the subsequent chapters are:

1. Do conductance readings taken *in vivo* compare with those taken with a laboratory set-up? If *in vivo* and *in vitro* readings are comparable further laboratory work is justified.
2. How sensitive and specific is electronic caries detection *in vivo* and *in vitro*, and how does electronic caries detection compare with visual examination, fibre optic transillumination and radiographic examinations?
3. Whilst some previously designed electronic caries detectors (the Caries Meter L) do not require an air supply, site specific readings suitable for use by clinicians do require the use of an airflow around the probe tip. The airflow can be varied in such electronic caries detectors and it is important to ask how differences in airflow effect electronic conductance/resistance readings?
4. Are electronic measurements able to assess both mineral content in enamel and lesion depth?
5. Can relatively untrained examiners use the new ECM II prototype and what level of intra- and inter-examiner reproducibility can be obtained?
6. Can a lower resistance scale, suitable for use without an airflow, be used to obtain overall resistance readings of a whole occlusal surface?
7. What recommendations can be made for the development of a new ECM?

The answers to many of these questions will be provided from laboratory studies and such studies are inevitably limited in the type and number of teeth available. The majority of teeth will be third molar and premolar teeth and it is appreciated that this sample is not necessarily representative of first and second molars.

To date, dentists diagnose occlusal caries by visual and radiographic means. However, a review of the literature has shown that visual examination is a poor predictor of caries status and that although the examination of bitewing radiographs improves clinical diagnosis, it can only be regarded as a "safety net" for large dentine lesions missed visually. Electrical resistance measurements have been shown to be a promising alternative method of occlusal caries diagnosis. However, before another electronic caries detector can be produced commercially further research is required. It is particularly important to establish the relationship between the resistance measurements and the caries status of the tooth. Although it would seem ideal to work on patients, this precludes histological examination to validate the status of the teeth. Thus an element of laboratory work is desirable. However, it is not known whether laboratory and clinical measurements correlate with each other and until such a correlation is established, laboratory work lacks credibility.

1. To calibrate two previously designed electronic caries detectors, the Vanguard electronic caries detector and the Caries Meter L, with a standard variable resistor.
2. To compare clinical (*in vivo*) and laboratory (*in vitro*) Vanguard readings on the

same teeth.

3. To validate the clinical electrical resistance measurements histologically.
4. To compare the electrical resistance diagnosis with conventional clinical and radiographic assessment.

2.2 Materials and method.

2.2.1 The machines and their calibration.

The Vanguard Electronic Caries Detector (Figure 2.1) generated an alternating square wave voltage (frequency 25 Hz), which, when used in the resistance range 0.5M Ω to 10M Ω , resulted in a very low current in the order of approximately 3 μ A. The resistance measurements were made between a probe tip, which was placed in the pits or fissures of teeth, and a hand held connector (Figure 2.2). The probe tip was placed centrally and coaxially within a stream of air so that, in clinical use, superficial saliva was removed, preventing surface conduction. The air supply was provided from the dental unit, via a coupling to the air rotor lead. Immediately after application of the probe tip to the tooth, the airflow was turned on using the foot control to the dental unit.

The machine gave three types of information to the dentist:

- 1 a face that frowned, indicating extensive demineralisation, or smiled, indicating a sound site (Figure 2.1).
- 2 a numerical reading on a scale 0 - 9, which was inversely related to the resistance and indicated increasing degrees of demineralisation. Thus the Vanguard scale was a conductance scale.

3 a bar chart indicating the stability of the reading.

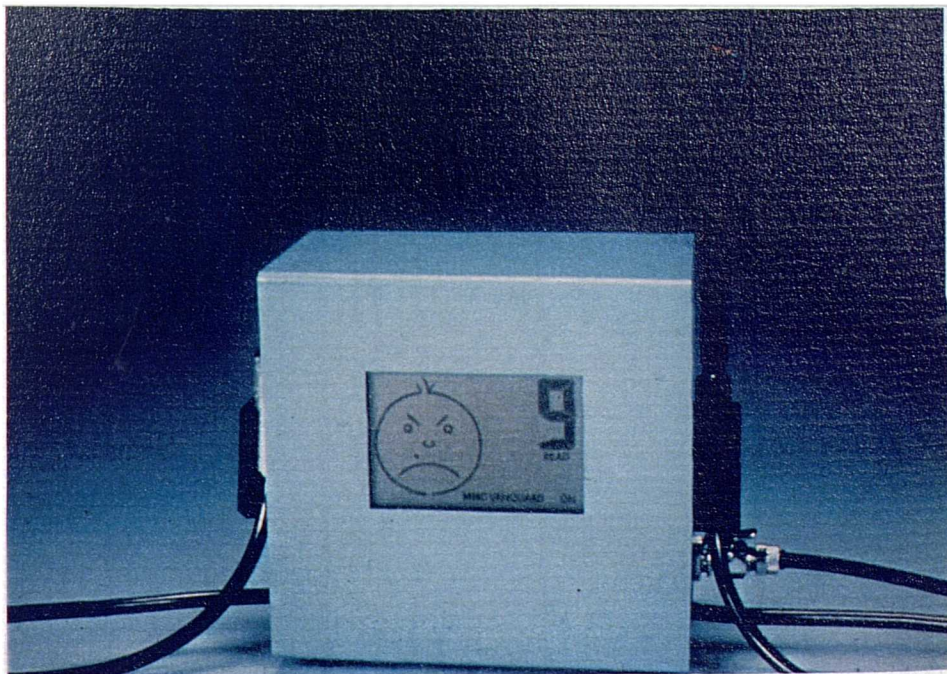
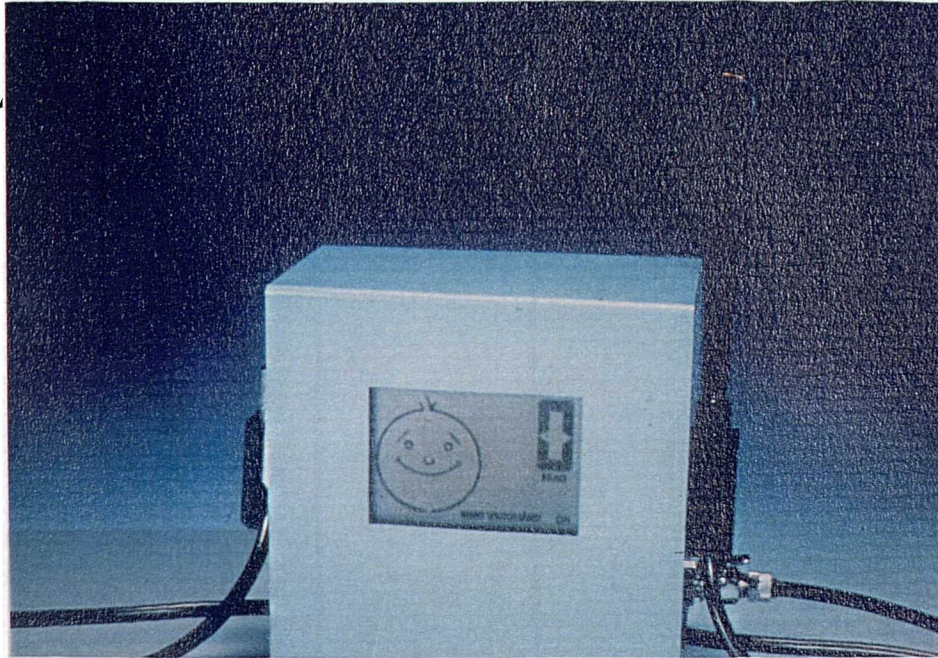


Figure 2.1 The display panel of the Vanguard electronic caries detector showing a sound (A) and carious (B) reading.

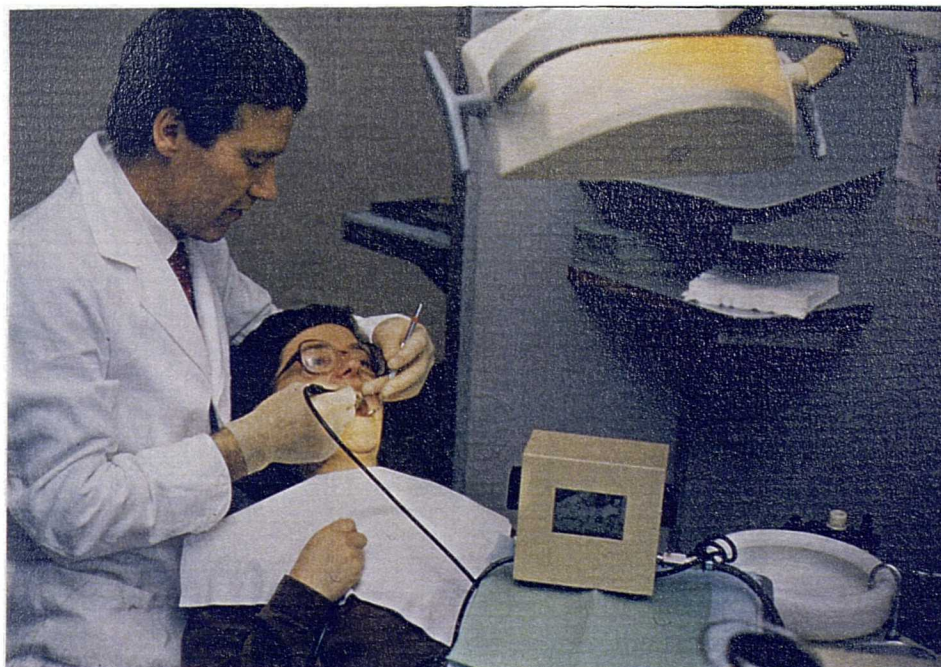
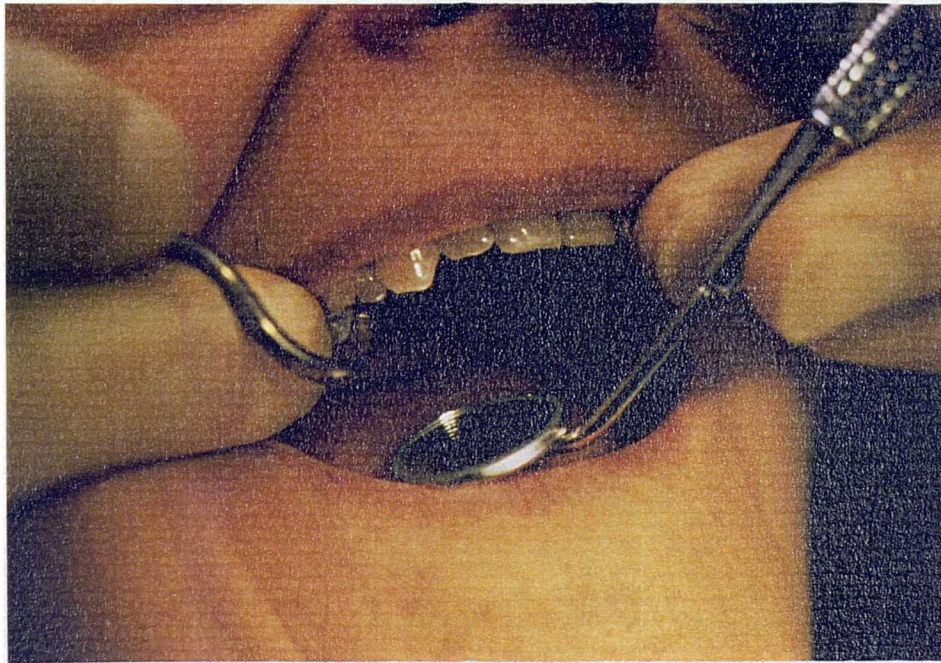


Figure 2.2 The Vanguard electronic caries detector in use. The probe tip is in a fissure (A) and the patient is holding the hand held connector (B). A shows the probe tip placed centrally and coaxially at the exit of an air supply tube.

On application of the probe tip to the tooth an audible bleep was heard and the bleep sounded again when the reading remained the same for 3 consecutive seconds. The final stable reading was displayed along with the appropriate facial symbol.

Calibration of the Vanguard was achieved by connecting a standard, variable resistance box (Beta-Ohm, Betatron, Sweden) between the probe tip and the hand held connector of the machine (Figure 2.3). Starting with a short circuit (i.e. no resistance), the resistance was gradually increased until the reading on the scale changed from 9 to 8. The resistance at which this change occurred was noted. The resistance was then progressively increased and the values at which the scale readings changed were recorded until a 0 reading was reached. This process was repeated for decreasing resistance. A lower and upper resistance value, and a mean for each Vanguard reading was obtained.

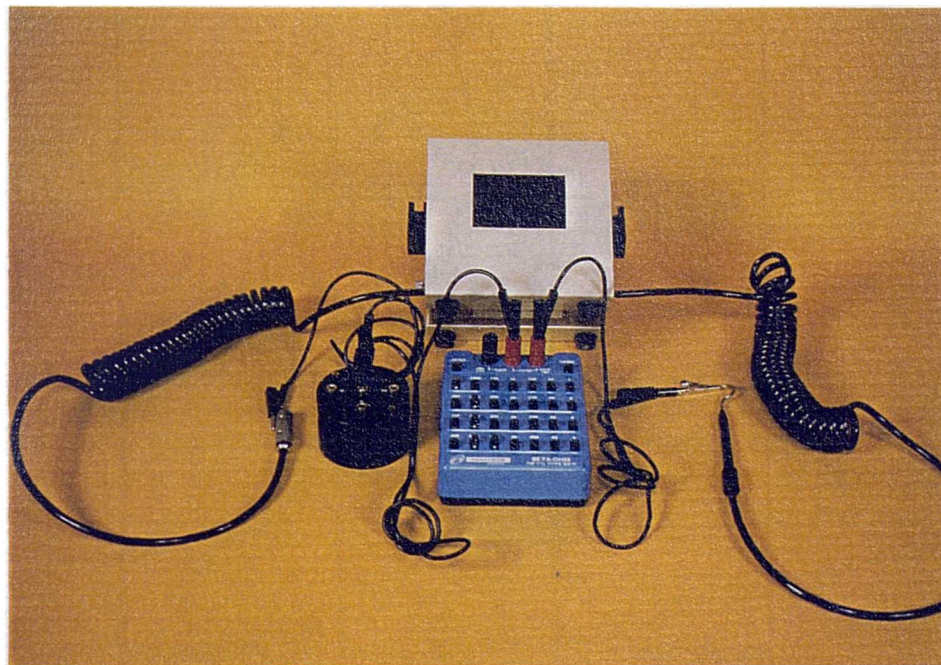


Figure 2.3 Calibration of the Vanguard electronic caries detector with a variable standard resistance box (Beta-Ohm, Betatron, Sweden).

The Caries Meter L (Figure 2.4). The Caries Meter L employed a much higher frequency, sinusoidal alternating voltage (400Hz) and resulted in an effective current of $1\mu\text{A}$. This machine was simpler in design and employed a different technique. There was no air supply to the probe tip so that in the clinical situation the teeth would need to be dried with a three-in-one syringe and isolated with cotton wool rolls to prevent "surface conduction" in saliva. To ensure a good electrical contact, the pits and fissures should then be moistened with a drop of saline, taking care not to over-wet the tooth. In clinical use, the resistance measurement was made between the probe tip and a clip attached to an oral electrode (Figure 2.5). Four coloured lights reflected the status of the tooth and the manufacturer's recommended treatment. A green light indicated no caries and no treatment. A yellow light indicated enamel caries, no treatment and continued observation. An orange light indicated dentine caries and the need for restoration and a red light indicated pulpal involvement and pulpal treatment. Before use, a simple calibration procedure was necessary. An adjust button was depressed to connect a built in resistor and an adjust knob turned until the orange light faded and the red light came on.

Calibration of the Caries Meter L was carried out in the laboratory by placing the standard resistance box between the probe tip and oral electrode, as for the Vanguard, and by increasing and decreasing the resistance and recording the values at which the lights changed colour.

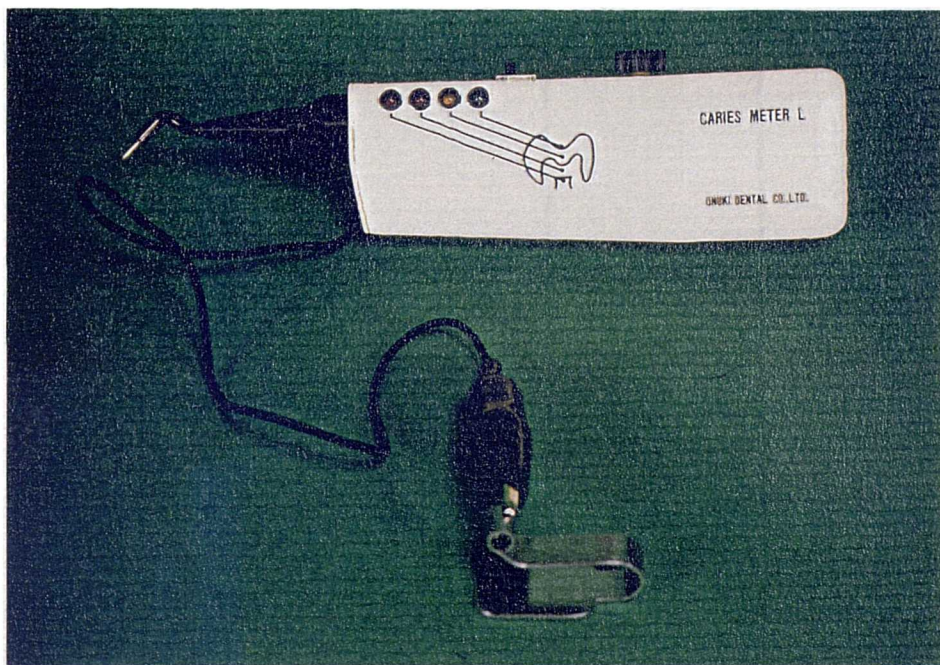


Figure 2.4 The Caries Meter L. The four coloured lights on the side of the machine are visible.

Figure 2.5 The Caries Meter L in use. The probe tip is in the fissure and the oral electrode is in place.



2.2.2 Patient selection and clinical measurements.

Twenty patients, requiring general anaesthetic extractions, were selected from a pre-operative assessment clinic. The patients were asked to participate in the study if they had one or more fully erupted teeth which required extraction. Forty teeth, with no visible sign of cavitation, were included in this study. Thirty eight of the teeth were third molars, the other two consisted of one first molar and one second premolar. From the patient's age, case history, and degree of tooth eruption, all teeth were assessed as having erupted two or more years previously. All patients had pre-operative radiographs of the teeth to be extracted.

The teeth were first cleaned with a prophylaxis brush and rinsed with the three-in-one syringe. A diagram or "plan" of the occlusal pit and fissure system was drawn for each tooth. One to four sites, which could be easily re-identified, were chosen per tooth and recorded on the plan. From the clinical examination each site was classified as:

- Sound fissure.
- Stained fissure.
- White spot lesion at entrance to fissure.
- Brown spot lesion at entrance to fissure.
- Undermining stain shining up through intact enamel.

The patient was asked to coat the tooth with saliva and allowed to rest so that the teeth could rehydrate from the drying procedure. Conductance readings were taken at each selected site using the Vanguard Electronic Caries Detector only, according to the

manufacturer's instructions. The teeth were given at least one minute to rehydrate between readings. Readings were taken at 100 sites.

The type of pre-operative radiograph and the radiographic caries status of each tooth was recorded by the author in consultation with a second dentist. Since occlusal enamel caries has been shown not to be visible radiographically (Rock and Kidd, 1988), the tooth was classed as either radiographically sound or as having dentine caries.

2.2.3 Extraction, laboratory measurements and histological validation.

Following extraction, the teeth were cleaned and placed in saline to which a few thymol crystals were added to inhibit further bacterial activity. Vanguard readings were repeated *in vitro*, together with Caries Meter L readings, by removing the teeth from the saline and holding them in the same hand as the hand-held or oral mucosa connector. Henceforth the electronic readings were conducted as per manufacturers' instructions. Between each reading the teeth were re-immersed in the saline to allow rehydration. Due to the unavailability of the Caries Meter L at the commencement of this study, readings were taken at only 76 sites on 32 teeth.

Histological validation was carried out on sections approximately 0.6mm thick. Sections were cut to include the entire area beneath the probe tip at each investigation site using a low speed diamond saw with water lubrication (labcut, Agar Scientific, Stanstead, UK). High definition, magnified, radiographic images (macroradiographs) were produced using a microfocal X-ray technique (Buckland-Wright, 1989), which will be described in detail in the next chapter. The investigation sites were classified, from the macroradiographs

obtained, as:

- Sound
- Caries confined to outer $\frac{1}{3}$ of enamel
- Caries in middle $\frac{1}{3}$ of enamel
- Caries to pulpal $\frac{1}{3}$ of enamel
- Dentine caries.

2.2.4 Statistical analysis.

The relationships between Vanguard readings *in vivo* and *in vitro* were assessed by application of the Spearman rank correlation test. The Vanguard readings were then grouped to provide dichotomous data; group 1, readings 0-3 and group 2, readings 4-9 and Cohen's kappa statistics applied. The difference between paired *in vivo* / *in vitro* readings was also calculated and the frequency distribution assessed.

The sensitivity and specificity of the diagnoses made by the Vanguard and Caries Meter L readings were calculated and compared with those obtained for the visual and radiographic assessments. This was done when both enamel caries and dentine caries were adopted as the diagnostic thresholds. When enamel caries was used as the diagnostic threshold, any lesion in enamel or dentine, determined from the histological validating technique, was regarded as caries. This will be referred to as the D_1 diagnostic threshold. When dentine caries was used as the diagnostic threshold, only histologically obvious dentine lesions were regarded as caries. This will be referred to as the D_3 diagnostic threshold. The terms D_1 and D_3 diagnostic threshold will be used in this context

throughout this thesis. Table 1.1 and section 1.3.2 and 1.3.3 (page 34) shows how percentage sensitivity and specificity were calculated. **Sensitivity** was the proportion of carious teeth correctly diagnosed while **specificity** was the proportion of sound teeth correctly identified.

2.3

Results.

2.3.1 Vanguard calibration.

Figure 2.6 shows for each Vanguard reading, 0-9 (x-axis), the corresponding lower and upper resistance values and the calculated mean.

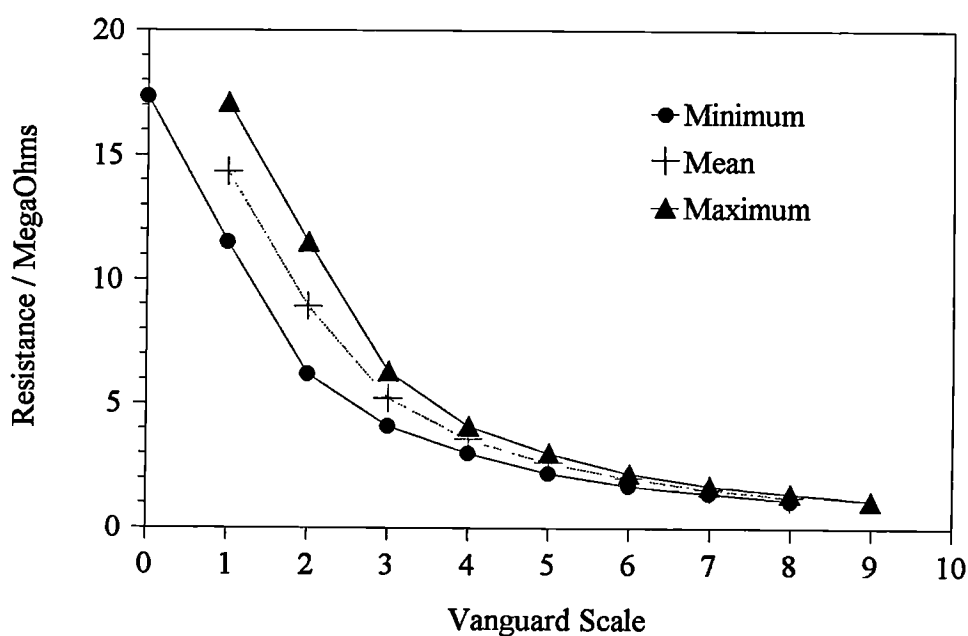


Figure 2.6 The minimum, maximum and calculated mean resistance values that correspond to each Vanguard reading.

2.3.2 Caries Meter L calibration.

Table 2.1 shows the resistance values that correspond to each of the coloured lights of the Caries Meter L. For comparison, the results obtained by Sawada *et al* (1986) are also included.

Table 2.1: The resistance values that correspond to the lights on the Caries Meter L.

Colour Light	Resistance Value in $M\Omega$	Resistance Value in $M\Omega$ (Sawada <i>et al.</i> 1986)
Green	> 1.41	> 0.6
Yellow	0.37 - 1.37	0.25 - 0.6
Orange	0.01 - 0.37	0.015 - 0.25
Red	< 0.01	< 0.015

2.3.3 *In vivo* and *in vitro* Vanguard readings.

Figure 2.7 shows the frequency distribution of the Vanguard readings taken *in vivo* and *in vitro*. The readings appear to be bimodally distributed about the 3 / 4 reading. Table 2.2 shows the distribution of sites by Vanguard readings, using a score 0-3 as indicating sound sites and 4-9 as indicating carious sites. Assuming the situation *in vivo* to be the "gold standard", then the *in vitro* model showed 86.5% sensitivity (agreement of carious readings) and 95% specificity (agreement of sound readings). Calculation of the Cohen's

kappa value (0.80) demonstrated an excellent association between the two groups.

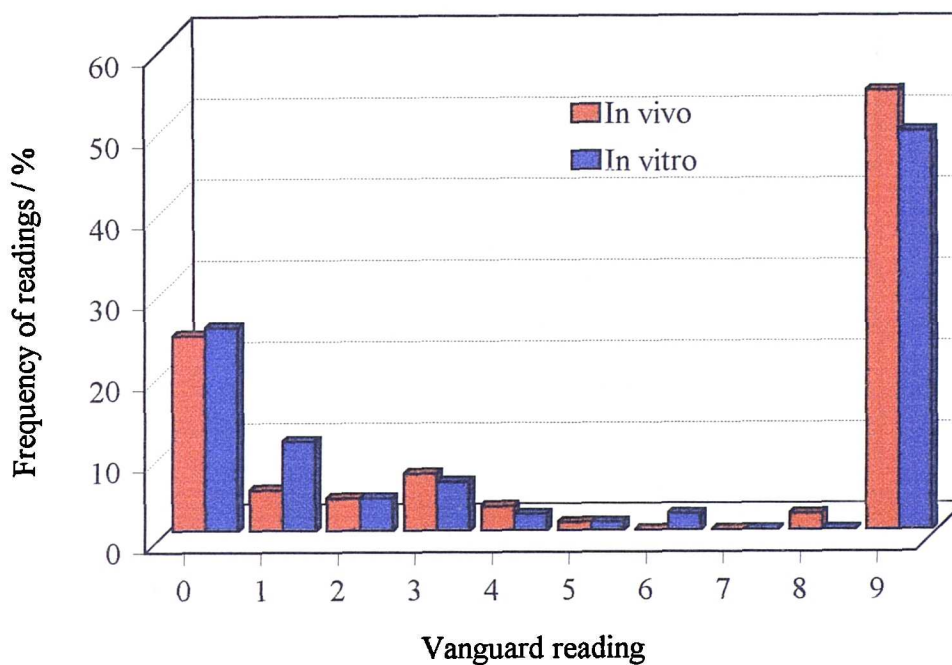


Figure 2.7 The frequency distribution of Vanguard readings taken in this study *in vivo* and *in vitro*.

Table 2.2: The relationship between *in vivo* and *in vitro* Vanguard readings.

		<i>In vitro</i> Vanguard readings		TOTAL
		0-3	4-9	
<i>In vivo</i> Vanguard readings	0-3	38	2	40
	4-9	8	52	60
TOTAL		46	54	100

A strong, statistically significant, direct relationship was found between Vanguard readings *in vivo* and *in vitro*. The Spearman rank correlation coefficient was 0.84 ($P < 0.001$). Readings *in vivo* and *in vitro* were identical in 72% of cases. If a difference of one value were accepted between the two readings, the agreement was 83%, and if a difference of three values was accepted, the agreement was 90%.

2.3.4 Histological validation.

One hundred sites were investigated. The macroradiographs showed that 36 sites were sound, 34 had enamel caries (6 in outer third, 6 in middle third, and 22 in pulpal third) and 30 had caries extending into dentine. Table 2.3 summarises the sensitivity and specificity values for all the diagnostic techniques at both the D_1 (enamel caries) and D_3 (dentine caries) diagnostic thresholds.

2.3.5 Visual examination (Table 2.4).

When the diagnostic threshold was set at the D_1 level, i.e. all enamel lesions and dentine lesions classed as carious, the sensitivity for the visual examination was 27% and the specificity 89%. These figures were calculated assuming that staining was due to physiological staining of sound fissures and that only white/brown spot lesions and undermining stain represented carious sites. Forty-eight percent of the teeth with deep enamel lesions or dentine lesions had stained fissures. Inclusion of stained fissures into the carious group resulted in an improved sensitivity (78%) but a lower specificity (53%).

When the diagnostic threshold was changed to the D_3 level (only dentine lesions classed as carious) and only undermining staining was thought to represent dentine caries from

the visual examination, the sensitivity was 3% and the specificity 97% (Table 2.3). Inclusion of stained fissures, and white and brown spot lesions, into the carious category resulted in a sensitivity for the visual examination of 80% but a specificity of only 39%. Of the histologically sound teeth 36% had stained fissures and of those with enamel caries 59% had stained fissures thus accounting for the lower specificity values.

Table 2.3: The sensitivity and specificity values (Sens & Spec) for visual, radiographic, Vanguard and Caries Meter L examinations, at both the D₁ (enamel caries) and D₃ (dentine caries) thresholds.

Type of exam	D ₁ (enamel caries) diagnostic threshold		D ₃ (dentine caries) diagnostic threshold	
	Sens	Spec	Sens	Spec
Visual	27%	89%	3%	97%
Radiograph	6%	100%	13%	100%
Vanguard <i>in vivo</i>	81%	78%	97%	56%
Vanguard <i>in vitro</i>	75%	83%	93%	63%
Caries Meter L	74%	74%	96%	62%

Table 2.4 The relationship between the clinical and histological appearance at the 100 investigation sites.

Histological appearance	Clinical appearance				TOTAL
	Sound	Stained fissure	White / brown spot	Undermining stain	
Sound	19	13	3	1	36
Enamel caries	8	20	5	1	34
Dentine caries	6	13	10	1	30
TOTAL	33	46	18	3	100

2.3.6 Radiographic examination (Table 2.5).

Dental panoramic tomograms were available for 80 of the sites and periapical radiographs were available for the remaining 20. The sensitivity and specificity of the radiographic examination was 6% and 100% respectively for the D_1 diagnostic threshold and 13% and 100% for the D_3 diagnostic threshold.

Table 2.5 The relationship between radiographic and histological appearance for the 100 sites.

Histological appearance	Radiographic Appearance		TOTAL
	Sound	Dentine caries	
Sound	36	0	36
Enamel caries	34	0	34
Dentine caries	26	4	30
TOTAL	96	4	100

2.3.7 Vanguard examination *in vivo* (Table 2.6).

When a Vanguard reading 0-3 was regarded as indicating sound sites and 4-9 as indicating carious sites, the sensitivity was 81% for the D₁ diagnostic threshold and 97% for the D₃ diagnostic threshold. The corresponding specificities were 78% and 56%. When the deep enamel lesions extending into the pulpal third of enamel were included with dentine lesions in the carious group, the sensitivity was 85% and specificity 66%.

Table 2.6 Relationship between Vanguard readings taken *in vivo* and *in vitro* and histological appearance.

Histological appearance	Vanguard reading				TOTAL
	<i>In vivo</i>		<i>In vitro</i>		
	0-3	4-9	0-3	4-9	
Sound	28	8	30	6	36
Enamel caries	11	23	14	20	34
Dentine caries	1	29	2	28	30
TOTAL	40	60	46	54	100

When only a 0 Vanguard reading was regarded as representing a sound site and readings 1-9 inclusive caries, a sensitivity of 89% and 100% was found for the D_1 and the D_3 diagnostic thresholds *in vivo*. However, the corresponding specificities were then 47% and 34% respectively. Compared with the results obtained when the Vanguard readings 3-4 were used as a cut-off between sound and carious, the sensitivities were minimally increased, but the specificities were unacceptably decreased.

2.3.8 Caries Meter L (Table 2.7).

The red indicator of the Caries Meter L (representing pulpal involvement) was never activated and the green indicator (representing sound sites) rarely lit. The majority of sites activated either a yellow (enamel caries) or orange (dentine caries) light. When the results

presented in Table 2.7 were analysed as recommended by the manufacturer, only 44% of the sites with enamel caries correctly lit the yellow light, while 52% lit the orange light and 4% lit the green light. When the sites with dentine caries were analysed, 96% correctly lit the orange light and 4% lit the yellow light.

Because the green light lit on only two occasions, any analyses done according to the manufacturer's instructions, that the green light only represented a sound site, would result in unacceptably low specificity values. However, when both the yellow and green lights were considered to indicate sound sites and the orange to indicate carious sites, the sensitivity and specificity were of the same order of magnitude as for the Vanguard *in vivo* and *in vitro* (Table 2.3).

Table 2.7 Relationship between Caries Meter L readings and the histological appearance.

Histological appearance	Caries Meter L readings			TOTAL
	Green light	Yellow light	Orange light	
Sound	1	19	7	27
Enamel caries	1	11	13	25
Dentine caries	0	1	23	24
TOTAL	2	31	43	76

2.4

Discussion

Figure 2.6 shows the calibration curve for the Vanguard electronic caries detector. It would appear that there is an "elbow" to the curve located around the Vanguard readings of 3 /4. Thus for Vanguard readings above 4, it takes smaller changes in resistance to effect the Vanguard reading and for readings below 3, larger changes. However, it should be noted that the Vanguard calibration curve demonstrated a logarithmic relationship. Despite this, the frequency distribution of Vanguard readings obtained was bi-modal, with more 0 and 9 readings being obtained (Figure 2.7), and an obvious division between readings 3 and 4, which was employed in this study as a cut-off point to separate sound and carious sites.

The resistance values obtained in the calibration of the Caries Meter L were lower than those for the Vanguard (Table 2.1). This can be explained by the different frequencies used and by the different ways in which the machines were intended to be used. The Vanguard probe tip was placed centrally in a stream of air; thus the area of contact made with the tooth was confined to the dimensions of the probe tip and the reading was therefore *site specific*. However, when the Caries Meter L was used a drop of saline was placed in the fissure to act as a contact medium. Since it was impossible to control the flow of the saline the area of electrical contact was larger. However, it has been shown that when the area of contact is increased the resistance values will fall (Hoppenbrouwers *et al.*, 1986); resistance values being approximately halved when the area of contact was doubled.

Laboratory studies are important when investigating a caries diagnostic technique because histological validation of the extent of the caries can be carried out. However, clinical features which might influence resistance measurements, such as temperature, saliva viscosity, saliva composition, and body resistance are not simulated in the laboratory. Despite the apparently crude laboratory experimental design, measurements taken *in vivo* and *in vitro* were remarkably consistent. This indicates that further experimental work on the development of a new resistance measurement device can be carried out in the laboratory on extracted teeth.

In this study the terms D_1 and D_3 were used to describe two diagnostic thresholds. The D_2 diagnostic threshold was not used in this study, but will be used in Chapter 4. In this thesis, the D_2 diagnostic threshold is referred to when sound sites and enamel caries confined to the outer half of enamel are both classified as sound and enamel caries in the pulpal half of enamel and dentine caries are classified as caries. These thresholds were determined by histological validation and it is important that these are not confused with those used in caries prevalence studies (Wenzel *et al.*, 1993). The most commonly used terminology refers to clinical examination and is:

D_1 = recognises all lesions detected as caries.

D_2 = excludes all "precavitation" lesions.

D_3 = excludes all enamel lesions and small cavities.

There is little agreement on the visual characteristics which indicate a sound or carious sites. In 1966 König suggested that staining was an indicator of dentine caries and in the

present study inclusion of fissure staining as an indicator of caries at the D_1 threshold led to an improved sensitivity of 78%, compared to 27% when excluded (Table 2.4). However, a marked fall in specificity from 89% to 53% accompanied this improved sensitivity. That is, if fissure staining, together with white and brown spot and undermining staining were to trigger restorative treatment, nearly half of the sound teeth would have been restored unnecessarily. However, if only undermining staining were assumed to indicate dentine caries then only 3% of lesions would be identified. Radiographic diagnosis of dentine caries fared little better as only 13% of dentine lesions would have been detected in this way.

The Vanguard manufacturer's instructions simply state that the 0 reading represents the most mineralised enamel and 8 or 9, severe demineralisation. Readings between 1 through to 7 then represent increasing degrees of demineralisation. However, pilot work carried out by White *et al.* (1978) used a cut-off resistance of 4 M Ω , below which a fissure was classed as carious. The cut-off Vanguard reading 3 / 4 adopted in this study would be in agreement with this, as the maximum resistance that gave a Vanguard reading of 4 was 4.128 M Ω . Analysis of the results obtained with the Vanguard machine showed high sensitivity for diagnosis at both the D_1 and D_2 diagnostic thresholds (81% and 97% respectively) when this cut-off was used. These results compared well with those reported previously and Table 2.8 presents salient information obtained from all studies in which the Vanguard and the Caries Meter L were used.

Table 2.8 Summary of previously published data on commercially produced electronic caries detectors.

Study	Number of teeth	<i>in vivo</i> / <i>in vitro</i>	Prevalence of caries / %	Validation technique	Diagnostic threshold	Electronic caries detector used & Diagnostic cut-off	Sensitivity / %	Specificity / %
White <i>et al.</i> , 1978	200 PM*	<i>in vivo</i>	43	Hemisection & murexide stain	? / D ₁	? 4 MΩ	72	98
Flaitz <i>et al.</i> , 1986	48 ML*	<i>in vitro</i>	50	Polarised light microscopy	D ₃	Vanguard 3/4	100 at 95 % confidence	100 at 95 % confidence
Rock & Kidd, 1988	48 PM* 2 ML*	<i>in vivo</i>	74	Polarised light microscopy	D ₁	Vanguard 0/1	70	85
Rock & Kidd, 1988	48 PM* 2 ML*	<i>in vivo</i>	74	Polarised light microscopy	D ₁	Vanguard 3/4	24	100
Rock & Kidd, 1988	48 PM* 2 ML*	<i>in vivo</i>	10	Polarised light microscopy	D ₃	Vanguard 3/4	80	89
Verdonschot <i>et al.</i> , 1992	4 PM* 19 ML*	<i>in vivo</i>	30	Cavity preparation	D ₃	Vanguard 3/4	96	71
Sawada <i>et al.</i> , 1986	3 PM* 15 ML*	<i>in vivo</i>	44	Cavity preparation	D ₃	Caries Meter L Yellow / orange light	100	100
Pieper <i>et al.</i> , 1986 Study A	54 ?	<i>in vivo</i>	50	Polarised light microscopy	D ₃	Caries Meter L Yellow / orange light	89	93
Pieper <i>et al.</i> , 1986 Study B	179 ?	<i>in vivo</i>	86	Cavity preparation	D ₃	Caries Meter L Yellow / orange light	77	92

* PM = Premolars and ML = Molars

D₁ = both enamel and dentine caries classified as carious.

D₃ = only dentine caries classified as carious.

The lower specificity value (56%) obtained in this study for the diagnosis of dentine lesions indicates 44% of sites with no dentine caries were classed as carious. However the machine was not actually far out because many of these teeth had deep enamel lesions, about to enter the dentine and when these were included in the analyses the specificity increased. Indeed had the histological validation been more accurate and lesion porosity in enamel and dentine measured, it might have been shown that the machine was always

right. It is possible that the machine is more reliable than the histological gold standard.

In this study the same Vanguard readings, 3-4, were used as a cut-off for both the D₁ and D₃ diagnostic thresholds and the potential of this diagnostic method was assessed in each case. Adoption of a different Vanguard cut-off, that is a Vanguard reading of 0 only as indicating a sound site, led to a minimal improvement in sensitivity but an unacceptable decrease in specificity. Thus it was not possible to determine two acceptable cut-off readings, one for each diagnostic threshold. The problem of reduced specificity may in part be explained by an inadequate airflow which would lead to a slow breakdown of the saliva film covering the tooth. This in turn would lead to lower resistance values or high Vanguard readings due to prolonged surface conduction to the gingival margin. In this study no attempt was made to control the airflow around the Vanguard tip. Improved airflow may overcome these lower specificity values in future equipment and this possibility will be investigated in further laboratory work.

Use of the Caries Meter L without air also resulted in good sensitivities for the D₁ and D₃ diagnostic thresholds (74% & 96% respectively). In this instance the lower specificity values (74% & 62%) may have been a result of the saline spreading to an adjacent area of the tooth with a deeper lesion. This adjacent area would give a lower resistance value than expected from the histological evaluation of the tested site. The uncontrolled spread of saline may also give an unacceptably large area of contact and lower resistance values. Thus, the Caries Meter L operates in a lower resistance range than the Vanguard and enables classification of investigation sites into four categories. Whether the resistance values that dictate these categories were correct needs further investigation. This initial

study would appear to indicate that reclassification of the Caries Meter L scale is required and this will be the subject of Chapter 7.

This study encourages the renewed interest in electrical resistance machines for the diagnosis of occlusal caries. It is a more sensitive and objective method of diagnosis than those currently employed in practice. Problems of specificity may be overcome by adjustment and quantification of airflow. Such studies can be carried out *in vitro* as the present study has shown the results from an *in vitro* model compared well with those obtained *in vivo*. Thus the effect of airflow on electrical conductance readings will be one of the subjects addressed in a laboratory study described in Chapter 4.

It is important to appreciate that while a low electrical resistance measurement may signify demineralisation, it does not indicate whether such a lesion is active or arrested. This information is important because active lesions require treatment (preventive and/or operative) but arrested lesions do not. Thus the value of resistance measurements may be that they can be repeated at recall. Comparing readings may indicate whether the lesion is progressing, static or even showing some remineralisation. For this, a number of criteria must be met by a new machine and these will be addressed in subsequent Chapters:

- The machine must be able to detect changes in the mineral content of the enamel, as well as changes in the comparatively gross classifications of caries depth used in this study (Chapter 3).
- The conductance or resistance scale must be conducive to measuring small

changes in resistance. The Vanguard scale, uses whole numbers which can represent a large resistance range, for example a Vanguard reading of 1 has a resistance range from 11.5 to 17.1 M Ω . The frequency distribution of Vanguard readings was found to be bimodal, with more 0 and 9 readings. The large number of 9 readings may have been because a Vanguard reading of 9 represents all resistance values of 1.1 M Ω or less. Thus a new machine produced with a continuous and expanded scale in the lower resistance range may provide more valuable information (Chapter 4).

- The readings must be reproducible for both the same operator (Chapter 4) and for different operators (Chapter 5), that is, it should show good intra- and inter-examiner reproducibility.

2.5 Conclusions.

The conclusions that can be drawn from this study are:

1. The Vanguard scale represents a logarithmic scale, inversely related to the resistance. The Caries Meter L scale, however, only has four classifications representing lower resistance values.
2. Clinical (*in vivo*) and laboratory (*in vitro*) Vanguard readings taken on the same teeth showed good comparability.
3. Electronic caries diagnosis resulted in a good sensitivity and acceptable specificity for the detection of enamel and dentine caries (81% and 78% respectively).
4. Electronic caries detection was more sensitive than either visual or radiographic examination for the diagnosis of occlusal caries.

CHAPTER 3:
THE RELATIONSHIP BETWEEN ELECTRICAL RESISTANCE
MEASUREMENTS, LESION DEPTH AND MINERAL CONTENT.

3.1 Introduction.

In Chapter 2, a re-evaluation of electrical conductance and resistance measurements, has supported renewed interest in these techniques for the diagnosis of occlusal caries. Unfortunately neither of the machines used are in production today. However, a Dutch manufacturer produced a prototype in 1990, called the Electronic Caries Meter I (ECM I). This new machine required evaluation supported by histological validation. Since it was shown in Chapter 2 that readings taken *in vivo* and *in vitro* were comparable, laboratory evaluation of the machine was justified. A particular point of interest in the evaluation of the new machine was the inter-relationship between the resistance measurements and the lesions in terms of both depth and mineral content.

Previous work by Rock & Kidd (1988) has shown that changes in electrical conductivity can allow detection of very early enamel lesions. However, the smaller the lesion detected by the electrical caries monitor, the more accurate the histological validation technique must be. Polarized light microscopy and microradiography will both detect early demineralisation (Gustafson & Gustafson, 1961) and allow both lesion depth and mineral content to be measured. However, sections have to be thinly ground to 100 μ m for these techniques. These thinly ground sections may miss the pathway of an electric current, which will take the route of least resistance (Rock & Kidd, 1988). For this reason use of

a thicker section, corresponding to the area under the machine's probe, is an attractive proposition so that an accurate picture of the demineralisation may be obtained. Thus a new histological technique allowing validation of such thick sections is required.

A high-definition microfocal X-ray unit has been described by Buckland-Wright (1989) and used clinically in the study of arthritides, metabolic disorders and some other bone diseases (Buckland-Wright & Bradshaw, 1989). The unit comprises a lanthanum hexaboride cathode and a single electromagnetic lens which focuses the electron beam onto an oil cooled multifaced tungsten target. The estimated X-ray source size ranges from 6-20 μm , compared to 600 μm for conventional units. By placing the object under investigation close to the X-ray source and the film at a distance, a magnified image called a macroradiograph can be obtained. The main advantage of the point source of X-rays is that high resolution macroradiographs can be obtained without blurring due to the penumbra effect. With the use of mammography film the spatial resolution was found to be excellent, allowing objects as small as 70 μm diameter to be detected with the use of X10 magnification (Buckland-Wright, 1989).

The present study had the following aims:

1. To validate resistance measurements taken with a prototype electronic caries meter (ECM I) in pits and fissures of sound and carious molar teeth.
2. To describe a histological validating technique, microfocal radiography, for use on sections approximately 0.65mm thick.
3. To investigate the inter-relationship between resistance measurements, depth of lesion penetration and mineral content in enamel and dentine.

3.2 Materials and Method.

3.2.1 Tooth selection.

Ten freshly extracted third molar teeth from 10 young adult patients were collected, cleaned and stored in Serets Normasol saline (Seton Healthcare Group, Oldham, UK) to which a few crystals of thymol were added to prevent bacterial growth. The teeth were fully erupted and had been present in the mouth for over two years. A detailed plan of the occlusal fissure pattern was drawn for each tooth and two to four discrete sites were chosen for resistance measurements and recorded on the plan. A total of 30 sites were investigated, none of which showed evidence of undermining staining of the dentine shining up through the enamel or cavitation.

3.2.2 Electrical resistance measurements.

Electrical resistance measurements were taken using a prototype electronic caries meter (Figure 3.1 (ECM I. P. Borsboom Sensortechnology & Consultancy B V, Westeremden, The Netherlands)). This machine consisted of a specially designed handpiece, similar to the Vanguard electronic caries detector in that it incorporated an air supply to, and around, a probe tip approximately $460\mu\text{m}$ in diameter. The air was provided by the three-in-one syringe on the dental unit. Gentle application of the probe tip to the investigation site was followed immediately by airflow to ensure that superficial saline was removed, preventing "surface conduction". Thus these readings, like those taken with the Vanguard, were also **site specific**. The roots of the teeth were held in the same hand as an electrical connector and the circuit was completed via an alternating, current supply (frequency 21Hz). Unlike the Vanguard, which had a conductance scale, the ECM I had a digital

display which gave resistance values at 0.5 second intervals. Initial readings were low due to momentary surface conduction, but as the tooth was dried, the resistance values increased. These readings were subjectively interpreted and once the readings appeared to stay the same for a minimum of three consecutive seconds, the reading was recorded as it was thought that this represented the true resistance value of the fissure. The teeth were re-immersed in saline between resistance measurements taken at each investigation site to ensure rehydration.

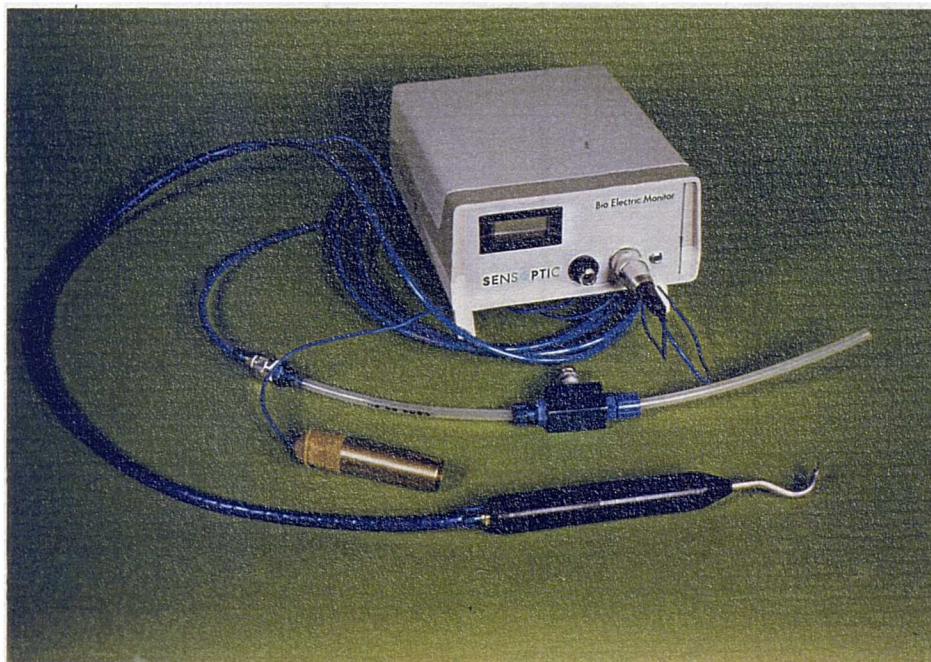


Figure 3.1 The first electronic caries meter prototype (ECM I).

3.2.3 Microfocal radiography.

The teeth were sectioned facio-lingually through each site to include the entire area under the probe tip. This was done using a low speed diamond saw, under water (Labcut, Agar Scientific, Stanstead, UK). The thickness of each section was measured using a Digimatic

micrometer (Mitutoyo, Japan). Each section was coded and a maximum of six were randomly mounted on card alongside a 6mm ball bearing and macroradiographs produced using the microfocal X-ray unit (Figure 3.2 (Astrophysics Research Ltd.)) operated at 60kVp, 0.95mA and exposed for 15 seconds (estimated focal spot size 6-12 μ m). The radiographic film used was Kodak Min-R Mammography film (Kodak, Hemel Hempstead, Herts. UK) with a Min-R rare earth intensifying screen. The latent images were automatically developed.

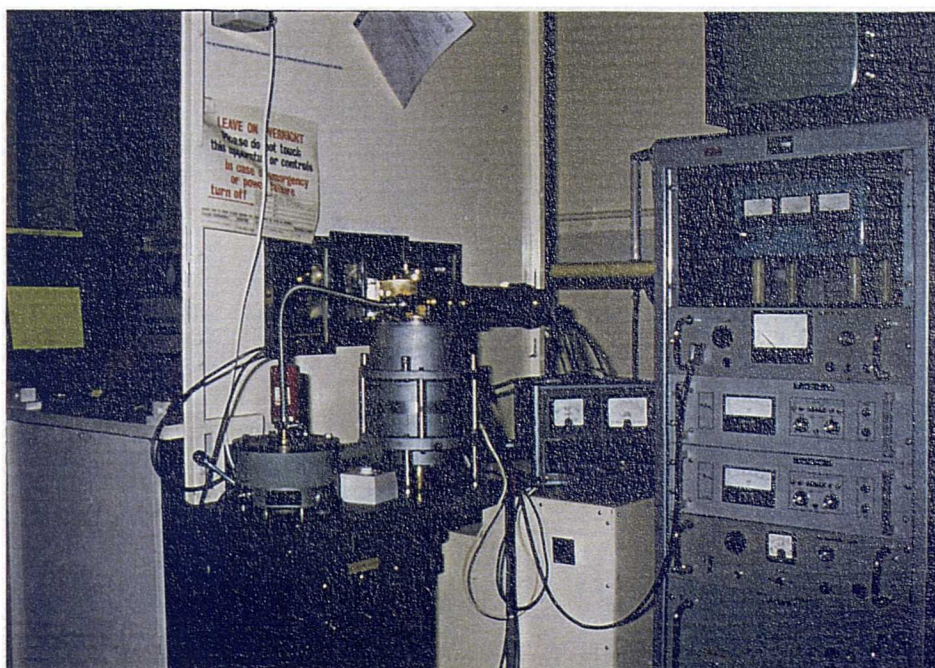


Figure 3.2 Microfocal X-ray unit, showing the X-ray generator in the foreground, a protective screen with window behind which the mounted tooth sections are placed and in the distance the yellow mounting card where the radiographic film is placed.

Both the electronic readings and the analysis of the macroradiographs were carried out by the same examiner (DNJR). To reduce the risk of introducing examiner bias, a minimum period of a week was allowed to elapse between the electronic examination and microfocal radiography. A further week was allowed to pass before the subsequent analysis of the macroradiographs. From the macroradiographs obtained (Figure 3.3), a subjective assessment of each investigation site was made and categorised as:

- Sound
- Caries confined to outer $\frac{1}{3}$ of enamel
- Caries in middle $\frac{1}{3}$ of enamel
- Caries to pulpal $\frac{1}{3}$ of enamel
- Dentine caries.

In order to analyse the macroradiographs, they were digitised using a high resolution CCD camera (Kodak Videk Megaplug) which provides 1280 by 1024 square pixels with 256 grey levels and a highly linear output. Using a Nikon Nikkor 55mm lens, films were digitised whilst backlit on a lightbox, the light output of which was adjusted until the optimum aperture (f/5.6 to f/8) of the lens could be used.

The digital output of the camera was connected to a Univision UPX1000 interface board and Univision UDC2600 display controller, both in an IBM-compatible 80486 PC, under the control of Optimas Software (Bioscan Inc U.S.). The image analysis system was used to capture and investigate the resultant images. Calibration of the image analysis system and the degree of magnification was determined by measuring the diameter of the 6mm ball bearing. On the captured image a line was drawn at right angles to the enamel

dentine junction (Figure 3.3), through what appeared to be the most demineralised part of any lesion present. The width of the line was set at 5 pixels so that grey level values could be integrated across the line to overcome noise and graininess of the film. Each point along the line was assigned a grey level and a plot of these values against distance from the surface of the tooth was obtained.

Such a plot can be seen in Figure 3.4, where high grey level figures represent radiopaque sites (light areas) and low figures, radiolucent sites (dark areas). Thus point A represents the grey level peak in the surface layer of the enamel lesion seen in Figure 3.3. Point B would therefore be the most demineralised site in the enamel and point C the least demineralised site in the enamel. The rapid fall in grey levels after point C represents the enamel-dentine junction (EDJ).

Quantitative measurements were made from these plots. The grey level value at the most demineralised site (B, Figure 3.4) and the least demineralised site (C, Figure 3.4) in the enamel, were determined for all of the samples. These values were expressed as a percentage of the mean grey value obtained from the middle of the sound buccal and lingual enamel of the same section. These percentage values will further be referred to as the percentage mineral content at the most demineralised and the least demineralised sites in enamel. For those lesions extending into dentine, the grey level just beyond the EDJ was also measured and expressed as a percentage of sound buccal and lingual dentine of the same section. This will be referred to as the percentage mineral content at the most demineralised site in dentine.

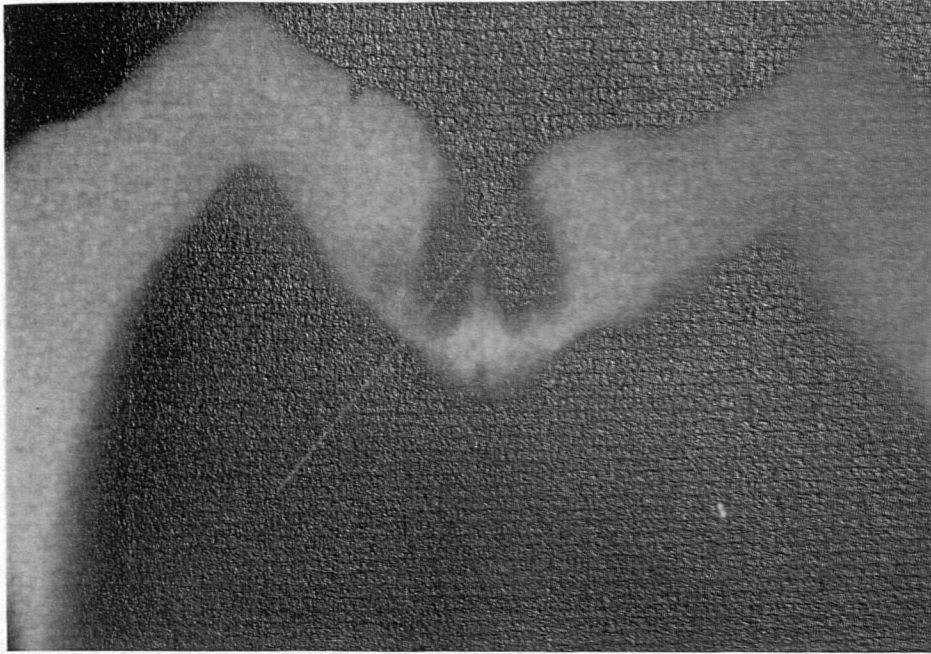


Figure 3.3 Captured image of the macroradiograph with investigation line through an enamel lesion on one side of the fissure.

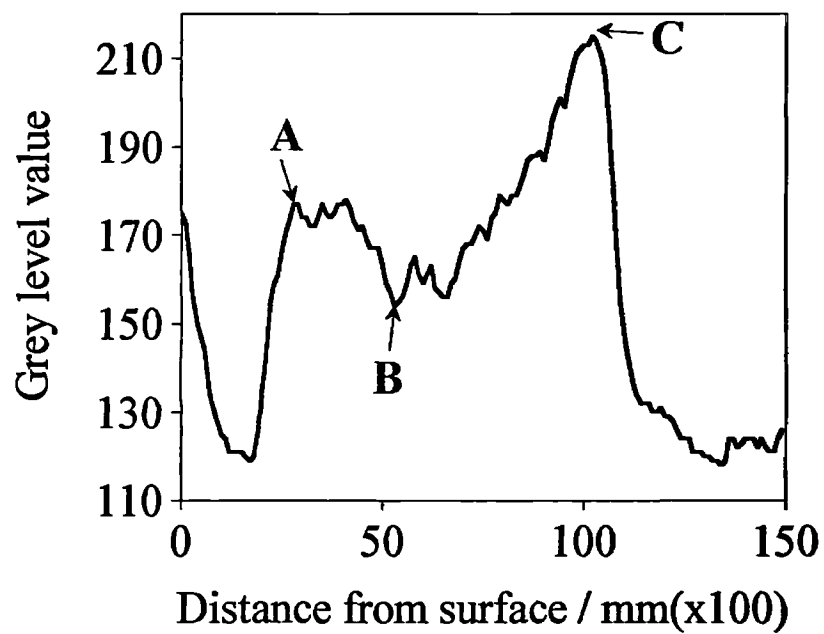


Figure 3.4 The resultant plot of grey level values against distance from the surface for the enamel lesion seen in Figure 3.3. A represents the grey level peak in the surface zone, B the most demineralised site and C the least demineralised site in the enamel lesion.

The depth of lesion penetration was measured by recording the distance of the advancing front of the lesion, whether in enamel or dentine, from the surface of the tooth. Where dentine caries was evident, the distance of the advancing front of the lesion from the EDJ was also recorded. The advancing front of the lesion in enamel was taken as being that point between the lesion and the EDJ at which the grey levels were highest. In dentine, the advancing front of the lesion was that point at which the grey levels returned to those of the sound buccal and lingual tissue.

3.2.4 Statistical analysis.

The sensitivity and specificity of the electrical resistance measurements were calculated for the D_1 (enamel and dentine lesions classed as carious) and D_3 diagnostic thresholds (dentine caries only classed as carious), using the results obtained from the subjective interpretation of the macroradiographs for validation. Different resistance values were chosen as cut-off points and the results presented as an ROC curve as described by Campbell and Machin in 1990 (see sections 1.3.2, 1.3.3 and 1.3.8; pages 34 and 36).

The Spearman Rank correlation test was used to estimate whether there was any relationship between resistance readings and the presence and depth of a carious lesion determined from the macroradiograph. The relationship with the percentage mineral content in the least and most demineralised area in enamel was also investigated for enamel lesions only and for enamel and dentine lesions.

The macroradiographs of six sections were randomly chosen and on a separate sitting a week later analysed in the same manner. The mean values for the percentage mineral

content in the least demineralised enamel were calculated for each pair of readings. The differences between the pairs of readings, and the mean and standard deviation of the differences were calculated and used to determine the limits of agreement and hence reproducibility (Bland & Altman, 1986; see section 1.3.9, page 41). This was repeated for the percentage mineral loss in the most demineralised region in enamel and dentine and the distance of the advancing front of the lesion from the surface of the tooth.

3.3

Results.

The mean thickness of the sections was 0.67mm (minimum 0.52mm, maximum 0.94mm). The enamel of two sections with extensive dentine caries was damaged on sectioning, which only allowed the depth of lesion penetration into dentine to be calculated. The radiographic images obtained were X4 magnification. Macroradiographs showed that 6 sites were sound and 24 had occlusal caries, of which 14 had dentine involvement.

Figure 3.5 shows the ROC curves generated for the D_1 and D_3 diagnostic thresholds. The resistance values chosen as the cut-off points below which a diagnosis of caries was made and above which indicated a sound site, are given in parenthesis. It can be seen that if resistance values above 50 M Ω indicate sound sites and values below 50 M Ω caries (either enamel caries or dentine caries), the sensitivity was 96% and the specificity 100%. However, this resistance value cut-off is unacceptably high and could lead to false positive results in a larger sample. A cut-off value of 2.2M Ω is more realistic and gives a sensitivity of 92% and specificity of 100% for enamel and dentine caries.

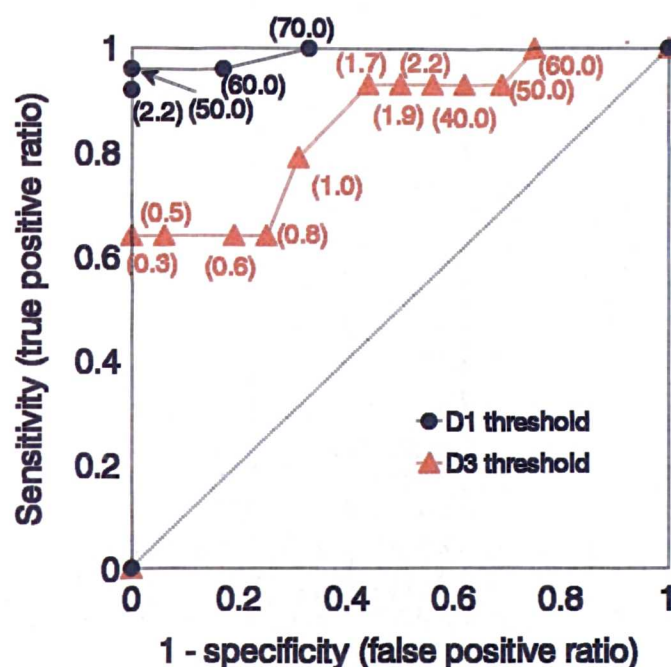


Figure 3.5 ROC curves for enamel and dentine caries (D_1 diagnostic threshold) and dentine caries only (D_3 diagnostic threshold). The different resistance cut-off values that resulted in the corresponding sensitivity and specificity values have been given in parenthesis and expressed in $M\Omega$.

These results can also be presented as in Table 3.1, to give three ranges of resistance value for clinical interpretation. A strong inverse relationship was found between the subjective interpretation of the macroradiograph and the resistance values ($r = -0.72$, $P < 0.001$).

Table 3.1 The relationship between resistance values and the subjective appearance of the macroradiograph.

Resistance/ $M\Omega$	Subjective assessment of macroradiographs		
	Sound	Enamel caries	Dentine caries
0 - 0.3	0	0	9
0.4 - 2.2	0	9	4
> 2.2	6	1	1
TOTAL	6	10	14

When the grey levels along the plot line were examined, it was noted that in all the sections with lesions in enamel, the whole thickness of enamel was affected by a degree of demineralisation. That is, at no site along the plot did the grey levels reach that of sound buccal or lingual enamel. This was in contrast to sections from teeth where there was no radiolucent area. In these sections the maximum grey levels of the sound occlusal enamel was comparable to that of the sound buccal and lingual enamel.

Quantitative analysis of the macroradiographs of all the investigation sites demonstrated that a strong direct relationship existed between resistance measurements and the percentage mineral content at both the most demineralised site (Spearman correlation coefficient $r = 0.75$, $P < 0.001$ (Figure 3.6 A)) and the least demineralised site in

enamel ($r = 0.77$, $p < 0.001$ (Figure 3.6 B)) as seen on the grey level plots. When the grey value of the least demineralised site fell below 96% of sound enamel the resistance recordings were less than $2.2\text{M}\Omega$ in all but two cases.

Concentrating on those carious sites whose resistance values varied from 0 - $2.2\text{M}\Omega$, there was a moderate direct relationship between the resistance value and the percentage mineral content at the least demineralised site in enamel ($r = 0.63$, $P = 0.003$). When the relationship between the percentage mineral content at the most and the least demineralised site from each optical density plot was compared, a strong direct relationship was found ($r = 0.89$, $P < 0.001$ (Figure 3.6 C)).

A moderate inverse relationship was found between the resistance measurement and the depth of lesion (as measured from the tooth surface to the advancing radiolucent front of the lesion in enamel or dentine) ($r = -0.62$, $P < 0.001$ (Figure 3.7 A)). However, when the carious sites whose resistance values were below $2.2\text{M}\Omega$ were investigated, only a moderate inverse relationship was found, which approached significance ($r = -0.41$, $P = 0.07$). When dentine lesions only were considered, no relationship was found between depth of penetration from the EDJ and resistance.

In enamel, the relationship between the percentage mineral content of the most demineralised site and the depth of lesion measured from the tooth surface was not marked ($r = -0.58$, $P = 0.018$ (Figure 3.7 B)). However, a very strong inverse relationship existed between depth of lesion in dentine as measured from the EDJ, and demineralisation on the dentine side of the EDJ ($r = -0.91$, $P < 0.001$ (Figure 3.7 C)).

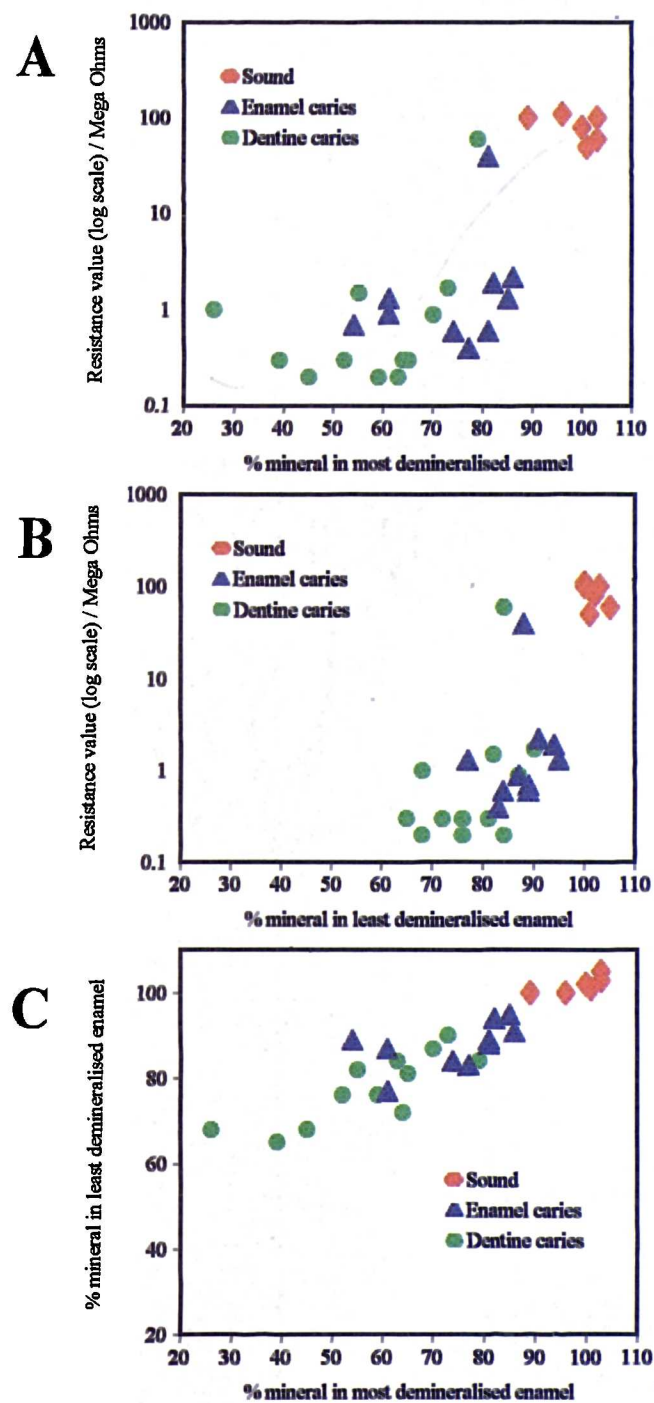


Figure 3.6 The relationship between resistance values (log scales) and the percentage mineral content in the most demineralised (A) and the least demineralised site (B) in enamel for all sites, including the enamel above dentine lesions, and the relationship between the percentage mineral content at the most and least demineralised site in enamel (C).

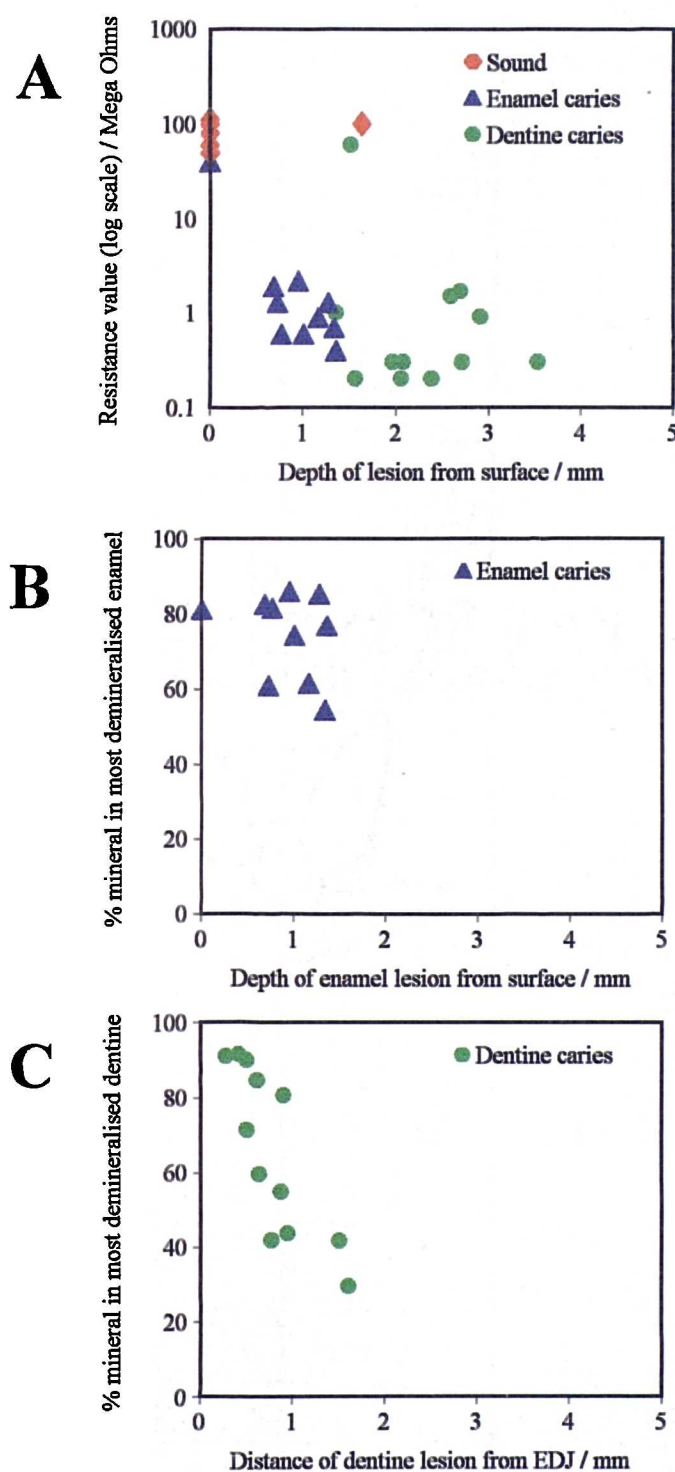


Figure 3.7 The relationship between resistance values (log scale) and the depth of lesion from the surface of the tooth (A), the percentage mineral content at the most demineralised site in enamel and depth of enamel lesion from the tooth surface (B) and the percentage mineral content at the most demineralised site in dentine and depth of dentine lesion from the EDJ (C).

The limits of agreement calculated for the percentage mineral content at the least demineralised site in enamel was $0.82 \pm 3.0\%$, where 0.82% was the mean of the differences between the first and second readings and 3.0% the possible error in results at the 95% confidence interval. This error is acceptable as it was a small proportion of the values being calculated. Similarly the limits of agreement for the percentage mineral loss at the most demineralised site in enamel was $0.48 \pm 1.96\%$ and for the percentage mineral loss in dentine was $0.58 \pm 4.02\%$. With regard to the distance of the advancing front of the lesion from the tooth surface the limits of agreement were not as good ($0.008 \pm 0.65\text{mm}$) because 0.65mm was a large error compared to the distances measured.

3.4

Discussion.

The aim of this study was to validate resistance measurements taken in pits and fissures of sound and carious molar teeth. Thick sections were selected for investigation as these appeared to correspond to the area under the probe of the electrical caries meter and as such, it was thought that a lesion was unlikely to be missed. The simplest form of validation was achieved by a subjective examination of lesion depth on the macroradiograph. This was found to correlate well with resistance measurements and the sensitivity and specificity calculated for occlusal caries diagnosis was found to be remarkably high (92% and 100% respectively) when the resistance value $2.2\text{M}\Omega$ was adopted as a cut-off point between sound and carious sites.

When the ECM I was used, the electric current that flowed would do so along a path of least electrical resistance. The lesion depth and mineral loss calculated from the digital

image analysis of the macroradiographs should therefore be measured along this pathway. However, this is likely to be a complex three-dimensional, tortuous course which is unlikely to follow accurately the investigation line used in this study. Serial sampling of the image of the enamel allowed the most demineralised area to be determined. Use of a straight investigation line through this point and perpendicular to the EDJ assumes some degree of symmetry of the lesion. This is, of course, not always the case and Figure 3.3 is an example. A steeper line would pass through the surface at the place of greater mineral loss, however, the depth measurements made from this line would be exaggerated due to its obliquity. To add to this problem initial enamel lesions frequently occur bilaterally on the wall of the fissure and current will pass along both pathways. The problem is complex and is simplified by the use of a single straight investigation line through one side of the fissure, which in the author's opinion, is a suitable representative compromise.

Optical density of a radiographic film is defined as \log_{10} of the ratio of the incident light to transmitted light intensity. This can be expressed as a function of the log of the relative X-ray exposure and represented diagrammatically as the characteristic curve of a film. The characteristic curve for the screen film used is typically *S* shaped, with a linear portion between a "toe" and "shoulder" (Whaites, 1992). The X-ray exposure of the sections was carefully controlled to ensure that the resulting macroradiographs occupied the linear part of the films characteristic curve (optical density 0.7 - 2.0). The CCD camera used to digitise the macroradiograph, produced an image with 256 grey levels and high degree of linearity. The darker the film, the lower the grey value and vice versa. Thus a close linear relationship between the film's optical density, grey value and mineral

content was ensured. However, no attempt was made to determine the relationship between absolute mineral content and grey values, other than to say that an obvious direct relationship over a large range of values existed between the two. To do more than this would complicate matters unnecessarily.

Accepting these limitations, valuable information can be obtained. To overcome the problem of the varying thicknesses of the sections, mineral content (or grey level value) was expressed as a percentage of the mean value from the middle of the sound buccal and lingual enamel of the same section.

There are potentially two ways of quantifying the severity of a carious lesion, namely the degree of demineralisation and the lesion depth. Having excluded the sound sites and concentrating on those lesions that gave a resistance value of less than $2.2\text{M}\Omega$, it was the degree of demineralisation in enamel ($r = 0.63$, $P=0.003$) which correlated more closely with resistance measurements than lesion depth ($r = -0.41$, $P = 0.07$). This is consistent with considerations of the theory underlying electrical conductivity measurements. In principle, if a layer of sound enamel (with poor conductivity / high resistance) separates areas of demineralisation from the dentine (with high conductivity / low resistance) conductivity overall would be very low.

The fact that degree of mineral loss, or lesion porosity in enamel, may influence resistance measurements more than lesion depth is of more than just academic interest. Only a moderate correlation was found between lesion depth in enamel and percentage mineral loss ($r = -0.58$, $P = 0.018$ (Figure 3.7 B)). Lesions of the same depth in enamel

may therefore differ in the amount of demineralisation and possibly in the potential for remineralisation. Thus, measurement of lesion severity in terms of mineral loss may be of clinical relevance. Electrical resistance measurements appear to be the only way that this assessment can be made quantitatively at the chairside and the technique should allow monitoring of lesion progression or arrest. The apparently lower limits of agreement for depth measurements may in part explain the lower correlation coefficient obtained. Small differences in positioning of the investigation line through the carious lesion obviously leads to greater errors for depth measurements than for the assessment of mineral loss.

A surprising result of this study was that no part of the enamel through the investigation traverse was mineralised to the same degree as sound buccal or lingual enamel, when an enamel lesion was present as a radiolucent area (Figure 3.6 C). This may explain the strong relationship between the resistance measurement and the percentage mineral content of least demineralised site in the enamel. It appears that mineral loss had occurred throughout the entire thickness of enamel and has thus opened up conductive pathways and lowered resistance. It can be argued that despite the carious process, sound enamel abutting fissures reaches a lesser degree of maturity and mineralisation than found elsewhere as a direct result of the development of the fissure (Boyde, 1989). However, this would not appear to be supported in this study because all of the six sound sites which gave high resistance values, had percentage mineral content figures of 100% or greater (Figure 3.6 B). That is, they were as mineralised or slightly hypermineralised compared to the sound buccal or lingual enamel.

Increased lesion depth in dentine was accompanied by increased demineralisation of the

dentine near the EDJ ($r = -0.91$, $P < 0.001$). However, in the present study, once caries had extended beyond the EDJ no change in resistance values occurred with progressively deeper lesions in dentine. However, Yoshida *et al.* (1989) suggested that an electrical caries monitor could measure the thickness of sound dentine left at the base of a cavity. Further work is required to assess whether expansion of the resistance scale in the range 0 - 2.2M Ω might make differentiation between dentine lesions of differing depths possible.

In this limited study, electrical resistance measurements have proved very sensitive and specific for occlusal caries diagnosis. However, no attempt was made to regulate any of the machine variables such as airflow, the pressure on the probe tip, time of application of the probe and probe tip dimensions, which may affect accuracy and reproducibility. Indeed, the continual display of varying resistance values meant that the final resistance reading recorded was at the operator's subjective interpretation. Initial work with the Vanguard and the ECM I has led to the subjective impression that airflow is critical to site specific readings described in this and the preceding chapter. Repeated measurements at obviously different airflows resulted in different readings with both machines, whereas other variables, such as the pressure applied to the probe tip, did not. Thus, further work needs to be done in these areas to develop optimum operational characteristics and these will be discussed in Chapter 4. Nevertheless, a relatively crude prototype has indicated that mineral loss in enamel may be more relevant to resistance values than the actual depth of lesion penetration. Thus the potential for monitoring lesion progression (demineralisation), arrest and regression (remineralisation) is evident.

3.5**Conclusions.**

The conclusions that can be drawn from this *in vitro* study are:

1. The ECM I prototype is highly sensitive and specific for occlusal caries diagnosis.
2. The microfocal radiography system described produced magnified images, or macroradiographs, of thick sections of teeth with a high resolution and no blurring suitable for image analysis.
3. Electrical resistance measurements correlated well with both lesion depth and mineral content in enamel. It would appear that the mineral content in enamel was the more important factor affecting measurements.

CHAPTER 4:

THE EFFECT OF AIRFLOW ON SITE SPECIFIC ELECTRICAL CONDUCTANCE AND RESISTANCE MEASUREMENTS.

4.1 Introduction.

The attraction of electronic caries diagnosis is that it has the potential to be sensitive and objective. However, the prototype ECM I described in Chapter 3 was relatively crude in that the machine relied upon a subjective interpretation by the operator to determine when the resistance value had become stable and should be read. The Vanguard electronic caries detector, on which the prototype was based, was set to deliver a reading when the conductance had remained the stable for three consecutive seconds. This time interval was set by the manufacturer and whether it was optimal for caries diagnosis was unknown. A second prototype produced by the Dutch manufacturer (ECM II) was designed to enable the optimum moment to take a reading to be investigated.

In Chapter 2, calibration of the Vanguard revealed a logarithmic relationship between the conductance readings and resistance. However, because the Vanguard had a discrete scale, the detection of small changes in resistance was restricted as each reading covered a range of resistances. In addition to this, the conductance scale only extended as far as 9, which accounted for all resistance values below 1.1 M Ω . Chapter 3 has shown that the majority of dentine lesions and some enamel lesions gave resistance values below this. Thus it is possible that the Vanguard could be improved by extending the scale in the low resistance range and making the reading continuous. For this reason an extended scale has been

incorporated in the second prototype. [Note that the Vanguard conductance scale and the ECM I resistance measurements are inversely related. That is high conductance readings corresponds to a low resistance and vice versa.]

In both the Vanguard and the ECM I, a probe tip was placed on specific sites on the occlusal surface. Airflow to and around the probe tip removed superficial saliva to prevent surface conduction of the current to the gingival margin and adjacent areas of the fissure so that **site specific** readings were obtained. Airflow was derived from the dental unit and a subjective observation was that the airflow was a critical variable affecting the these readings. Since the machines did not allow quantification of the airflow, this apparent variation of the airflow and its relevance to the readings obtained could not be investigated. The new prototype ECM II incorporated a flow meter which allowed the relevance of airflow to be scientifically investigated.

The preceding chapters have supported renewed interest in electronic caries detection for use in pits and fissures. Use of the first prototype electronic caries meter (ECM I) has shown that the basic design enabled both the presence and extent of occlusal caries to be determined. The strong correlation found between resistance measurements and mineral content in enamel has demonstrated the possibility of monitoring the progress, arrest and remineralisation of lesions. This, however, will only be possible if the same examiner can accurately obtain the same reading at a second examination, that is there must be good intra-examiner reproducibility. Failure to do this may give the false impression that a lesion is progressing / arresting simply due to a lower / higher second resistance reading due only to poor repeatability.

The present laboratory study had the following aims:

1. To calibrate a second ECM II prototype (with a continuous and extended conductance scale) and graphic recorder against a variable standard resistance.
2. To investigate the relevance of airflow to electronic conductance and resistance measurements.
3. To determine the optimum interval over which electronic conductance or resistance measurements should be taken.
4. To determine the relationships between the optimum conductance or resistance measurement and the mineral content in enamel and depth of the lesion if present.
5. To investigate the intra-examiner reproducibility of readings taken at the optimum settings.

4.2 Materials and Method.

4.2.1 The ECM II prototype (Figure 4.1).

The ECM II consisted of a hand-held connector and a specially designed probe connected to an alternating current supply (sinusoidal waveform, 21Hz) similar to the ECM I. The probe tip (diameter 0.46mm) was placed coaxially in the centre of an air tube of internal diameter 1.8mm. The ECM II demonstrated modifications that were made to the ECM I, which included a flow meter linked to the air supply so that the airflow around the probe could be altered and quantified. The air supply was provided by the dental unit via a coupling to the air rotor lead and activated by a foot control peddle. The display panel on the ECM II box gave a conductance reading similar to the Vanguard caries detector.

However, the ECM II differed in that the scale was expanded from a range of 0-9, as used by the Vanguard, to a range of -0.45 - 13.25. The ECM II scale was also continuous and inversely related to the resistance placed between the probe tip and hand-held connector. That is, the reading was a **conductance** measurement. When a circuit was completed between the probe tip and the hand held connector, an audible bleep was heard. A second double bleep was heard and the final conductance reading displayed when the conductance value had remained between the same two whole numbers for 3 consecutive seconds. This was regarded as a **stable conductance reading**.

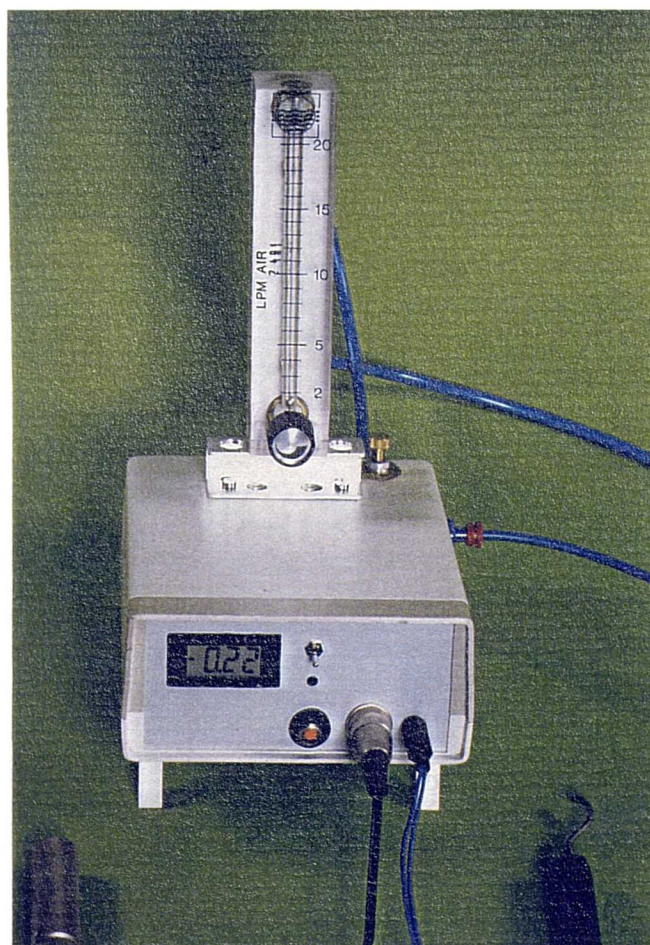


Figure 4.1 The second prototype electronic caries meter (ECM II) with fitted airflow meter.

In this study the ECM II was connected via an insulated optico-electric safety device (Figure 4.2 A) to a mains driven graphic recorder (Figure 4.2 B). The recorder enabled the continuous output from the ECM II to be recorded even after the stable conductance reading was displayed.

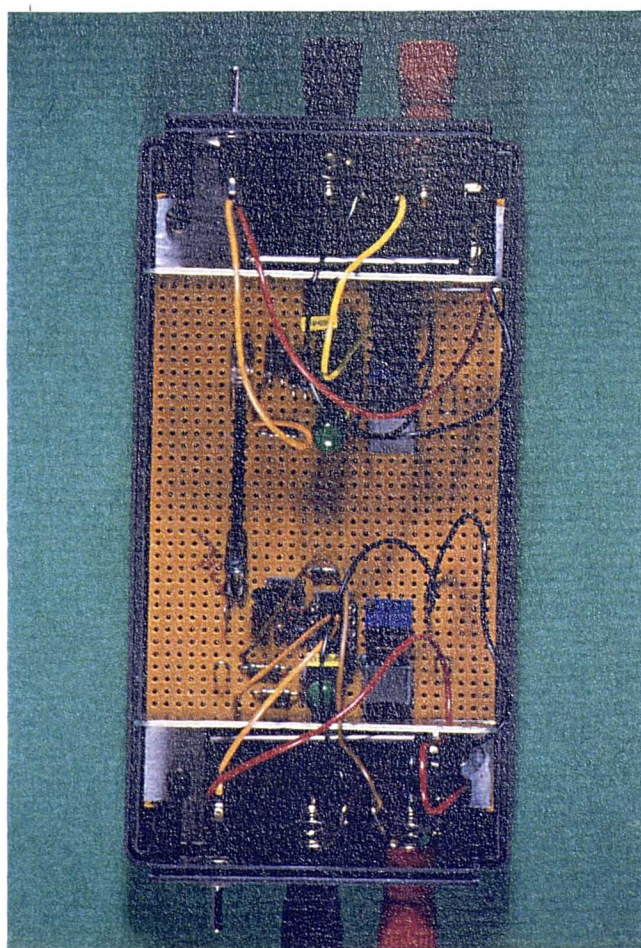


Figure 4.2 A Optico-electric safety device, with cover removed, via which the ECM II was connected to the mains driven graphic recorder.

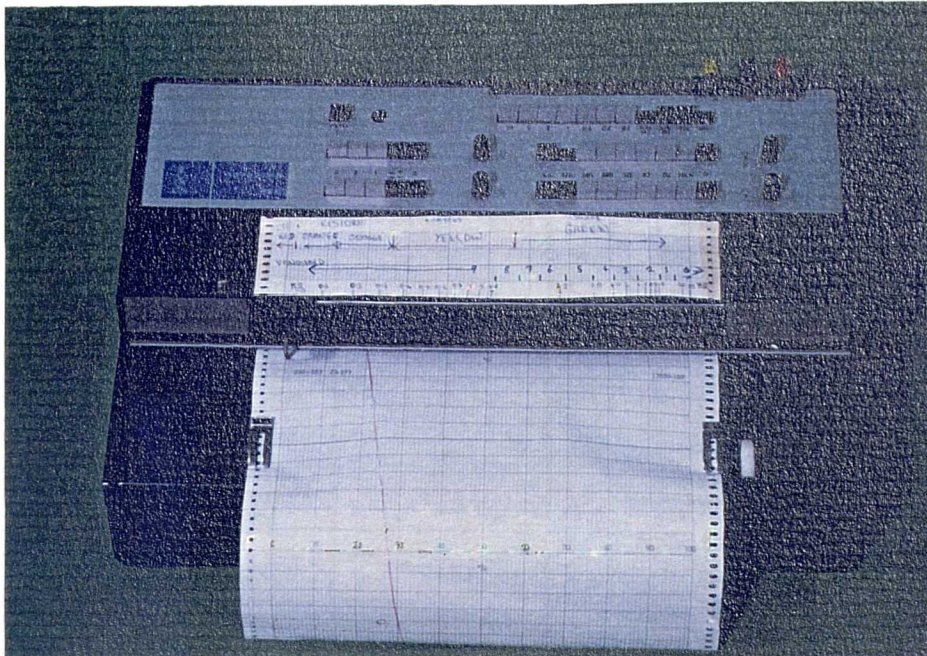


Figure 4.2 B The graphic recorder.

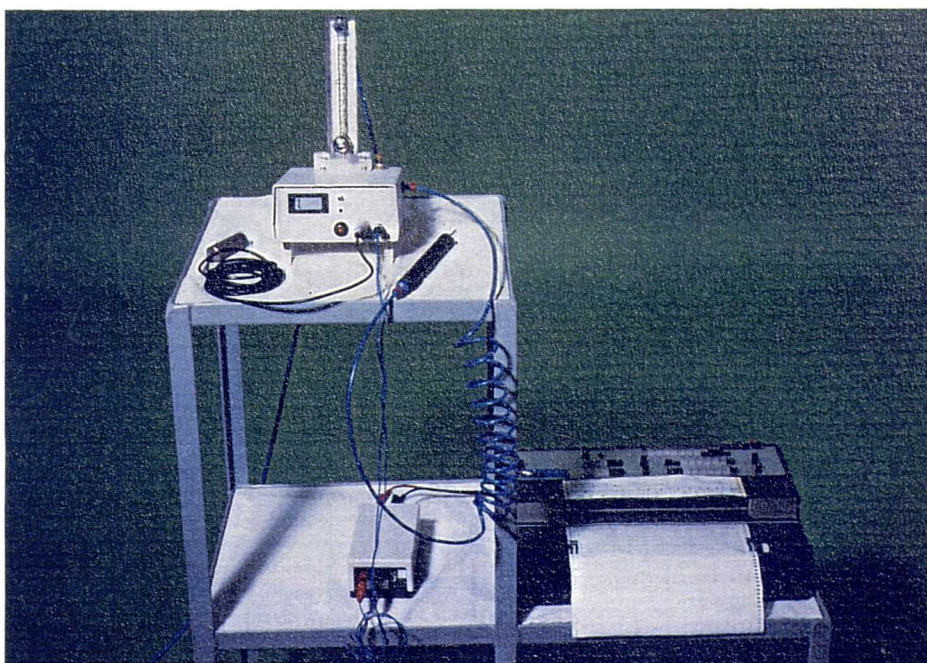


Figure 4.2 C The ECM II connected to the mains driven graphic recorder and the optico-electric safety device.

4.2.2 Calibration of the ECM II and the graphic recorder.

Calibration of the ECM II conductance reading was achieved by connecting a standard, variable resistance box (Beta-Ohm, Betatron, Sweden) between the probe tip and the hand held connector of the machine. Starting with a short circuit (i.e. no resistance), the resistance was gradually increased until the reading on the scale changed from 13 to 12.99. The resistance at which this change occurred was noted. The resistance was then progressively increased and the values at which the readings changed whole numbers were recorded until a 0 reading was reached. This process was repeated for decreasing resistance. Thus, a lower and upper resistance value was obtained for each whole conductance reading.

The recorder was calibrated in a similar manner. Initially the probe tip was placed in direct contact with the hand held connector to represent zero resistance, and the stylus of the recorder adjusted to zero on the graph paper. The standard, variable resistance box (Beta-Ohm, Betatron, Sweden) was then connected between the probe tip and hand held connector of the ECM II. The resistance value was increased by set amounts and the position of the stylus that corresponded to each resistance value was marked on the recorder.

4.2.3 Study sample.

Thirty two extracted teeth, with no visible sign of cavitation, were included in this study. Thirty of the teeth were third molars, the other two consisted of one first molar and one second premolar. The teeth were selected from those used in Chapter 2 which were extracted from 14 patients, whose age, case history, and degree of tooth eruption

indicated that all the teeth had been erupted for two or more years.

The teeth were first cleaned with a prophylaxis brush and rinsed with the three-in-one syringe. A diagram or "plan" of the occlusal pit and fissure system was drawn for each tooth. One to four discrete and easily re-identifiable sites, were chosen per tooth and recorded on the plan (total 76 sites). The visual appearance of the sites varied; 27 (36%) appeared sound, 15 (20%) had evidence of white or brown spot lesions at the entrance to the fissures, 31 (41%) had stained fissures and 3 (4%) had evidence of undermining stain of the dentine shining up through apparently intact enamel. The teeth were stored in saline to which a few crystals of thymol were added.

4.2.4 Resistance measurements.

Resistance measurements were taken by holding the roots of the tooth in the same hand as the hand-held connector. The paper feed of the recorder was switched on to run at 1mm per second. The probe tip was placed at the investigation site and airflow immediately supplied around it by depressing the foot control on the dental unit. The airflow was set prior to taking any readings by adjustment of the knob on the front of the flow meter which, once set, automatically remained constant throughout each reading when activated. The graphic recording of resistance was continued for approximately 15 seconds. The stable conductance reading displayed on the ECM II was noted for each site. Negative stable conductance readings were recorded as a zero reading. Subsequently, the resistance values at 1 second intervals following the commencement of the reading could be calculated from the calibrated, graphic recording. Due to the limited deflection of the graphic recorder's stylus, the maximum resistance recordable in this manner was 40 MΩ.

Therefore, once this resistance had been reached, all subsequent 1 second readings were recorded as 40 M Ω , despite the fact that the resistance probably increased further. When multiple readings were taken on the same tooth, it was placed back in saline for at least 2 minutes to ensure rehydration between readings.

Stable conductance readings and resistance values at each second interval were recorded for each investigation site at three different airflows: 5 l/min; 7.5 l/min; and 10 l/min. The airflow was measured from the maximum diameter of the ball bearing in the flow meter. At least a week was allowed to elapse between readings at the different airflows to reduce the effect of examiner bias. Readings were repeated at each airflow on one site of 27 teeth (36% of the total sample) enabling reproducibility to be assessed. At least a week was allowed to elapse between readings.

4.2.5 Histological validation.

Facio-lingual sections of the teeth were prepared as described in Chapter 3 (page 96), so that the entire area under the probe tip was included on the section. Macroradiographs of the sections were produced using microfocal radiography and analysed using an image analysis system (page 98). The image analysis system was used to determine the percentage mineral content at the most and least demineralised site in enamel and the depth of lesion penetration from the surface of the tooth for all investigation sites. If no lesion was present, the depth of lesion penetration was recorded as 0 mm. Where dentine lesions were present, the percentage mineral content in dentine at the most demineralised dentine just beyond the EDJ and the distance of the advancing front of the lesion from the EDJ were recorded. The advancing front of the lesion in enamel was taken as being

that point between the lesion and the EDJ at which the grey levels were highest. In dentine, the advancing front of the lesion was that point at which the grey levels returned to those of the sound buccal and lingual tissue.

Both the electronic readings and the analysis of the macroradiographs were carried out by the same examiner (DNJR). To reduce the risk of introducing examiner bias, a minimum period of a week was allowed to elapse between the completion of electronic examinations and microfocal radiography. A further week was allowed to pass before the subsequent analysis of the macroradiographs. From the macroradiographs obtained a subjective assessment of each investigation site was made before the quantitative analysis and categorised as:

- Sound
- Caries confined to outer ½ of enamel
- Caries to pulpal ½ of enamel
- Dentine caries.

4.2.6 Statistical analysis

The sensitivity and specificity of the stable conductance readings were calculated for different levels of caries diagnosis, using the results obtained from the subjective interpretation of the macroradiographs for validation. The levels of caries diagnosis, or diagnostic thresholds were determined from histological validation and were:

- D₁ which included any lesion in enamel or dentine as caries.
- D₂ which included lesions in enamel and dentine deeper than outer half of enamel as caries and excluded enamel lesions in the outer half of enamel.
- D₃ which included only dentine lesions as caries and excluded all enamel lesions.

The D₁ and D₃ diagnostic thresholds were consistent with those described in Chapters 2 (page 76) and 3 (page 101). For each level of caries diagnosis, different conductance values were randomly chosen as cut-off points, below and including which the site was classified as sound and above which was classified as carious. The sensitivity and specificity values for each cut-off value was calculated and the results presented as an ROC curve as described by Campbell and Machin in 1990 (see section 1.3.8, page 36). This was repeated for stable conductance readings taken at each airflow.

Cumulative resistance values were calculated by adding the resistance values obtained at 1 second intervals. This was repeated for the three airflows, for periods up to and including 10s. At airflows 7.5 and 10 l/min only, this was continued up to and including 15s. The cumulative resistance values after each time interval were analysed in the same way as the stable conductance readings. However, because resistance and conductance measurements were inversely related, cumulative resistance readings above and including the chosen cut-off were regarded as sound and those below as carious.

From the ROC curves generated the area under the curve was calculated using a calibrated image analysis system (SeeScan, SeeScan Solitaire, SeeScan Imaging Ltd.

London, UK). The optimum sensitivity and specificity values were determined by the point closest to the top left corner of the graph, and the cut-off value recorded. The highest sensitivity value obtained when the specificity was greater than 93% was also recorded with the relevant cut-off value.

Cumulative resistance measurements for periods up to and including 15 seconds were investigated further. After each time period, the mean cumulative resistance measurement and standard deviation was calculated for the sound sites only. Using these figures the lower 95% confidence limits were calculated. Sound sites and sites with dentine caries represent two extremes of the carious process, therefore readings taken at these two different types of sites should not overlap. Thus, cumulative resistance values obtained for dentine lesions should only appear below the lower confidence limit for sound sites and the proportion of readings taken of dentine lesions which were below the lower confidence limits for sound sites were calculated. Readings taken of enamel lesions were not included in these analyses.

The stable conductance readings and cumulative resistance readings, taken at different airflows, were investigated using the Spearman Rank correlation test to establish whether there was any relationship between these readings and the presence and depth of a carious lesion determined from the macroradiograph. The relationship with the percentage mineral content in the least and most demineralised area in enamel was also investigated for all the sites. For those lesions extending into dentine, the relationship between the various electronic readings and percentage mineral content in the most demineralised dentine and depth in dentine from the EDJ were also investigated.

Reproducibility was assessed only for those readings which proved optimal for caries diagnosis by calculating the limits of agreement, intraclass correlation and kappa value for dichotomous data using the cut-off values which gave the optimum sensitivity and specificity. Limits of agreement were established according to Bland and Altman (1986) by calculating the mean value of the first and second readings, and the difference between the readings, and plotting the difference against the mean (see page 41). The mean of the differences (d) was calculated together with the standard deviation (SD). The limits of agreement between which 95% of the readings will lie, when repeated, were then represented by $d-2SD$ and $d+2SD$ (or more precisely $d-1.96SD$ and $d+1.96SD$).

4.3

Results.

4.3.1 Calibration of the ECM II and graphic recorder.

Figure 4.3 A shows the minimum, maximum and calculated mean resistance value that corresponds to each whole ECM II conductance reading. The results obtained for the Vanguard electronic caries meter are also presented for comparison. It is clear that calibration of the two machines against a physical model (the variable resistor) produces similar results. The calibration curve of conductance readings represents a logarithmic scale. Calibration of the graphic recorder also demonstrates that the output from the ECM II or deflection of the stylus and corresponding resistance, are logarithmically related (Figure 4.3 B).

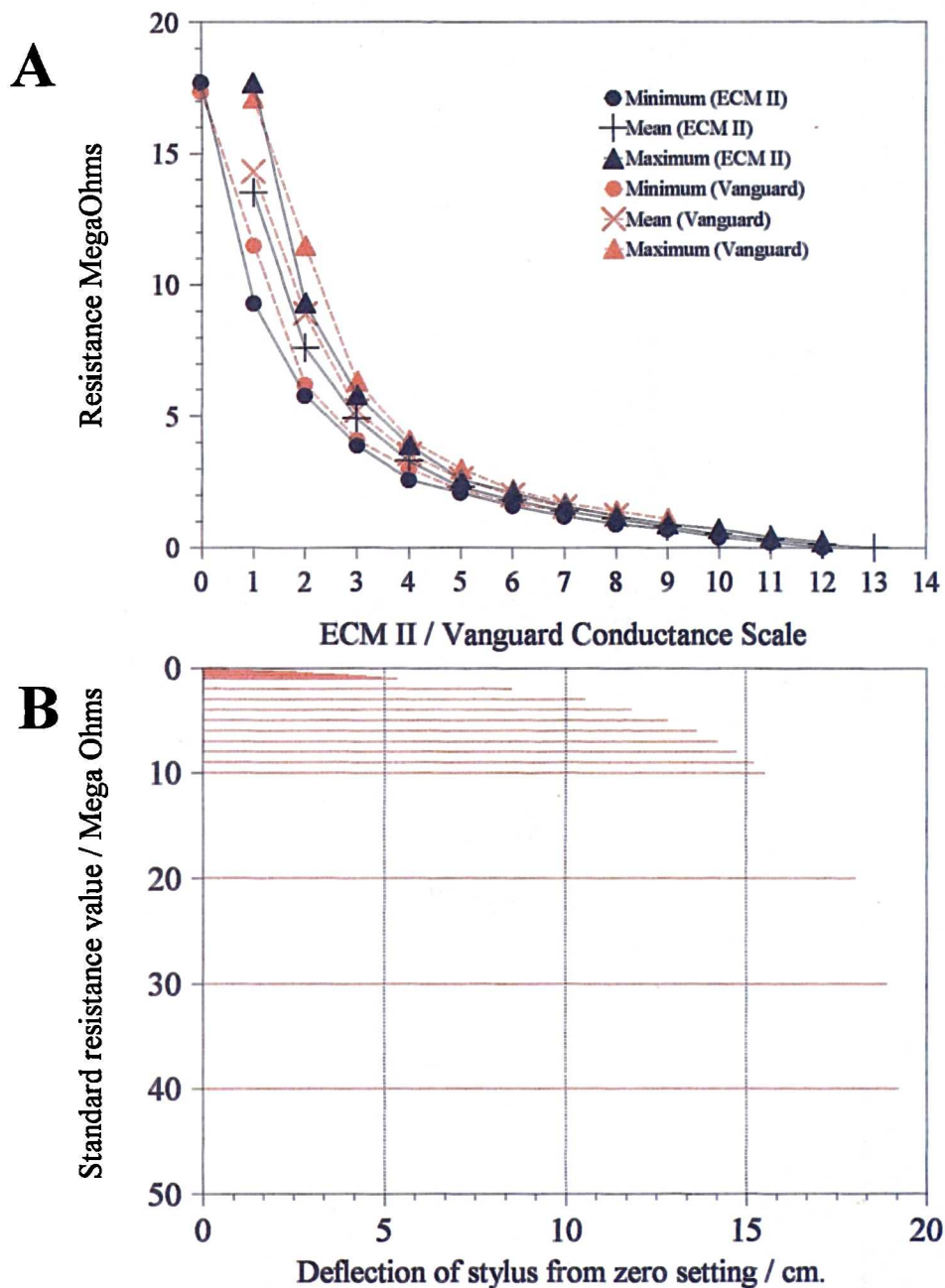


Figure 4.3 Calibration curve for the ECM II stable conductance scale, showing the minimum, maximum and calculated mean resistance that corresponds to each whole number on the conductance scale and for comparison the corresponding results obtained for the Vanguard (A). Calibration of the graphic recorder, showing the resistance value and the amount of stylus deflection (B).

4.3.2 Histological validation.

Subjective examination of the macroradiographs obtained for each section showed that 27 sites (36%) were sound, 25 sites had enamel caries (33%) and 24 sites had dentine caries (32%). Of the 25 sites which had enamel lesions, 10 were confined to the outer $\frac{1}{2}$ and 15 extended through to the pulpal $\frac{1}{2}$ of enamel.

4.3.3 Stable conductance and cumulative resistance measurements.

Figure 4.4 shows graphically the resistance values obtained at 1 second intervals from a typical sound site, an enamel lesion and a dentine lesion. For each classification, three different graphs representing the three different airflows are shown.

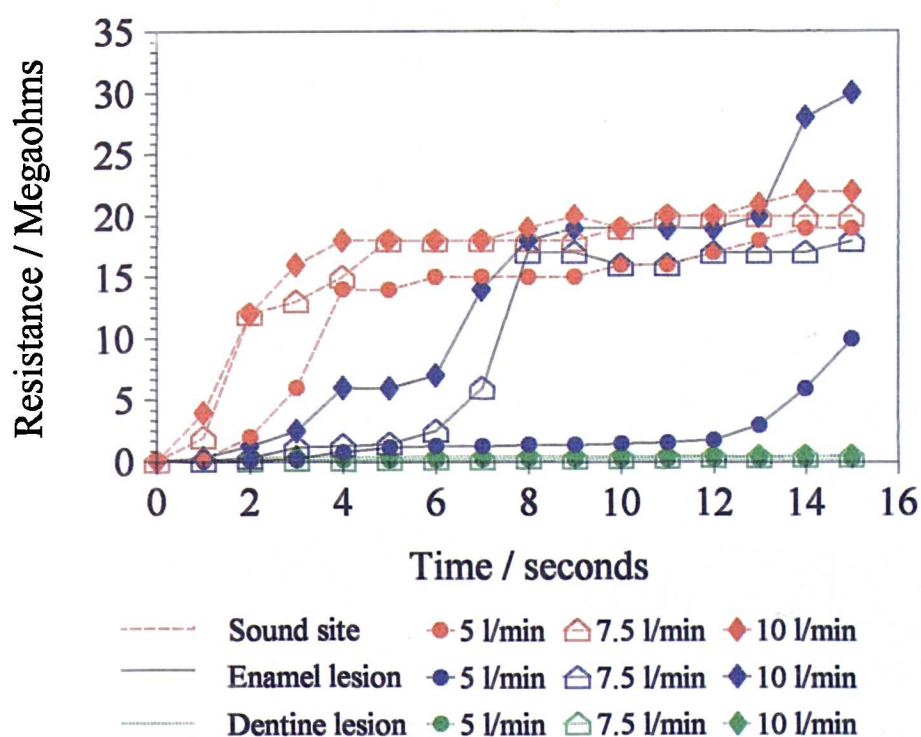


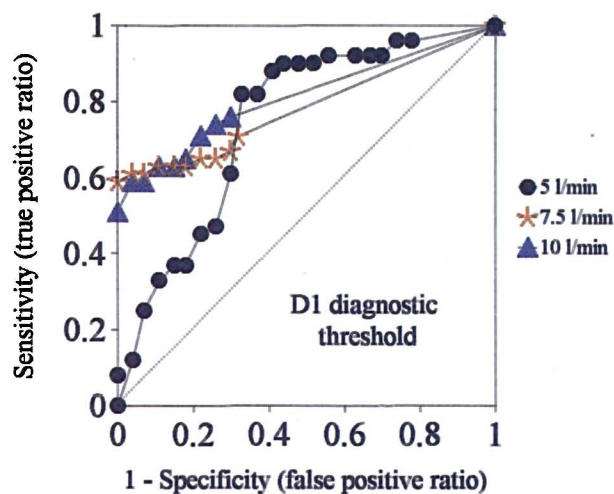
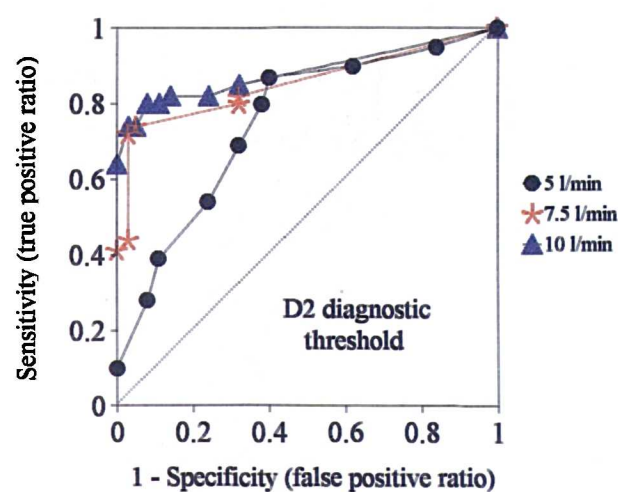
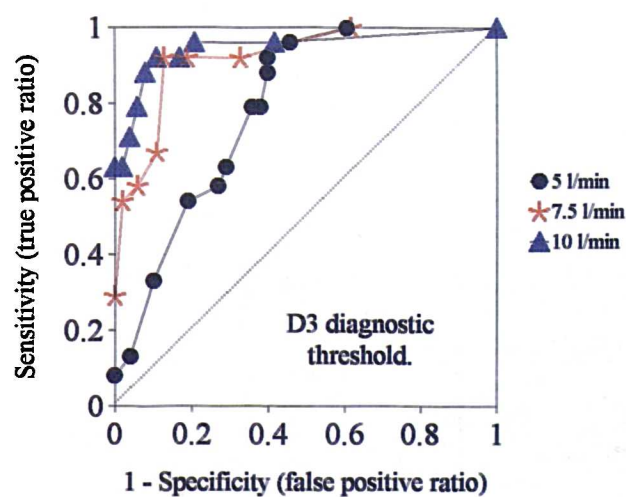
Figure 4.4 Graphic representation of the resistance values obtained at one second intervals for a typically sound site, an enamel lesion, and a dentine lesion.

It can be seen that for the sound site the resistance rose rapidly whilst for the dentine site the resistance remained low throughout. The enamel lesion also gave a high resistance but after a longer period than the sound site. Interestingly, the difference between readings taken at different airflows was more marked for the enamel lesion, which at 5 l/min rose very little over the first 12 seconds.

Figure 4.5 A-C shows the ROC curves obtained when the **stable conductance readings** were investigated for the D_1 , D_2 and D_3 levels of caries diagnosis respectively. At each level of caries diagnosis an ROC curve was generated for each airflow.

Figure 4.6 A-D shows the ROC curves obtained when the **cumulative resistance readings** obtained after 2, 6, 10, and 15 seconds respectively, were investigated for the D_1 level of caries diagnosis. Graphs A and B have three ROC curves representing the three different airflows, graphs C and D have two ROC curves representing airflows 7.5 and 10 l/min only. Similarly, Figures 4.7 A-D and 4.8 A-D show the ROC curves obtained for the **cumulative resistance readings** at the D_2 and D_3 levels of caries diagnosis respectively.

Tables 4.1, 4.2 and 4.3 summarises the optimum sensitivity and specificity values, sensitivity values obtained when the specificity was greater than 93% and the corresponding cut-off values for each type of reading and diagnostic threshold. The area under each ROC curve is also presented. For full details obtained for cumulative resistance readings after 2, 4, 6, 8, 10, 12, 14 and 15 seconds see Appendices I, II, and III, pages 245-247.

A**B****C****Figure 4.5 A-C**

ROC curves constructed for stable conductance readings at the D₁, D₂ and D₃ diagnostic threshold respectively. At each diagnostic threshold, three curves are presented for readings taken with an airflow of 5, 7.5 and 10 l/min.

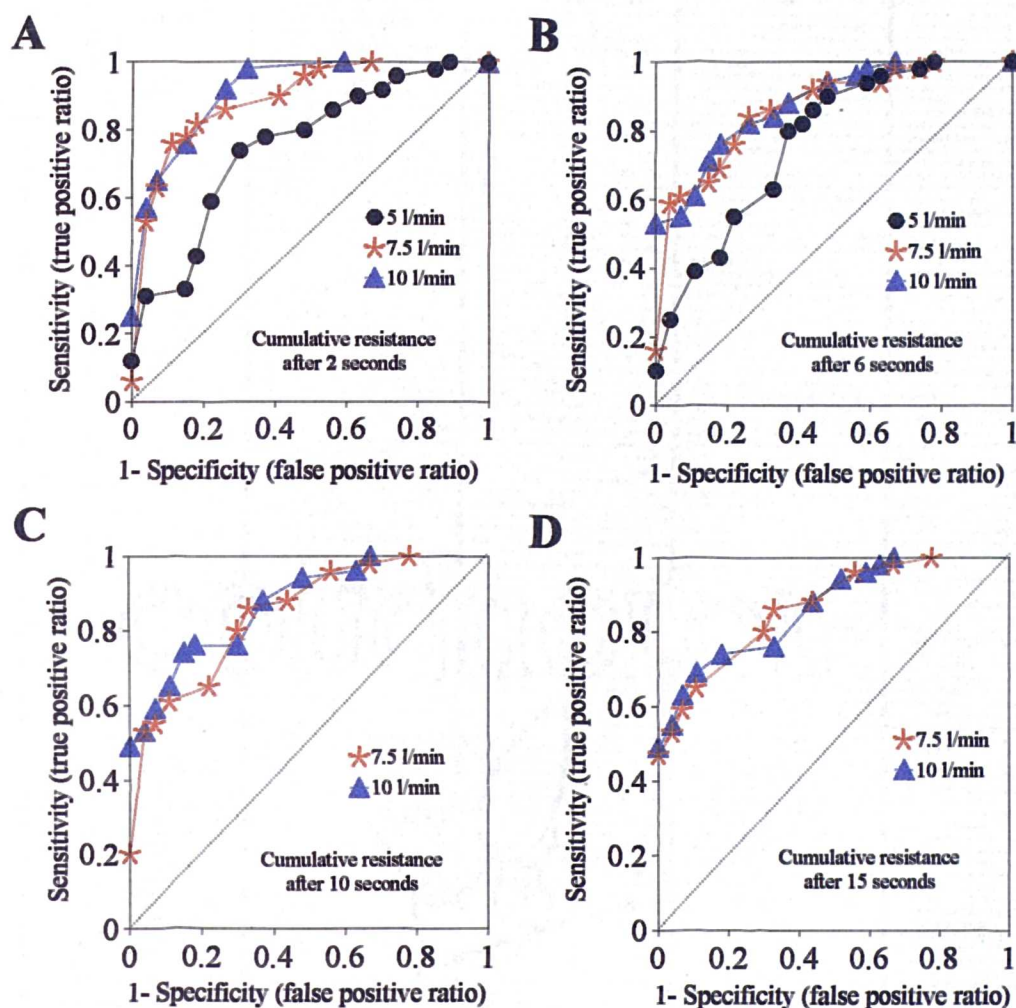


Figure 4.6 A-D ROC curves obtained for cumulative resistance readings obtained after 2, 6, 10 and 15 seconds respectively for the D_1 diagnostic threshold. A and B have three curves for readings taken with an airflow of 5, 7.5 and 10 l/min while C and D only have curves for readings taken at 7.5 and 10 l/min.

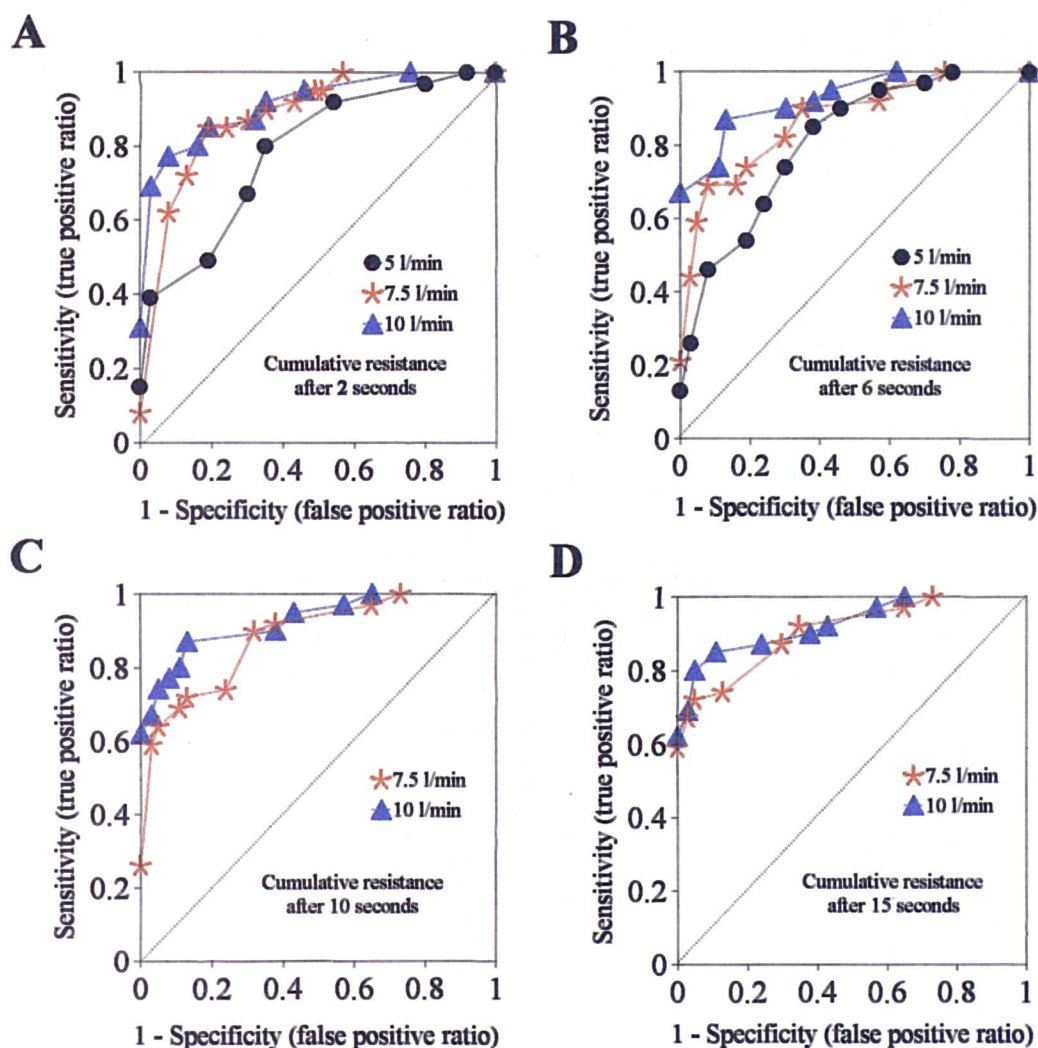


Figure 4.7 A-D ROC curves obtained for cumulative resistance readings obtained after 2, 6, 10 and 15 seconds respectively for the D_2 diagnostic threshold. A and B have three curves for readings taken with an airflow of 5, 7.5 and 10 l/min while C and D only have curves for readings taken at 7.5 and 10 l/min.

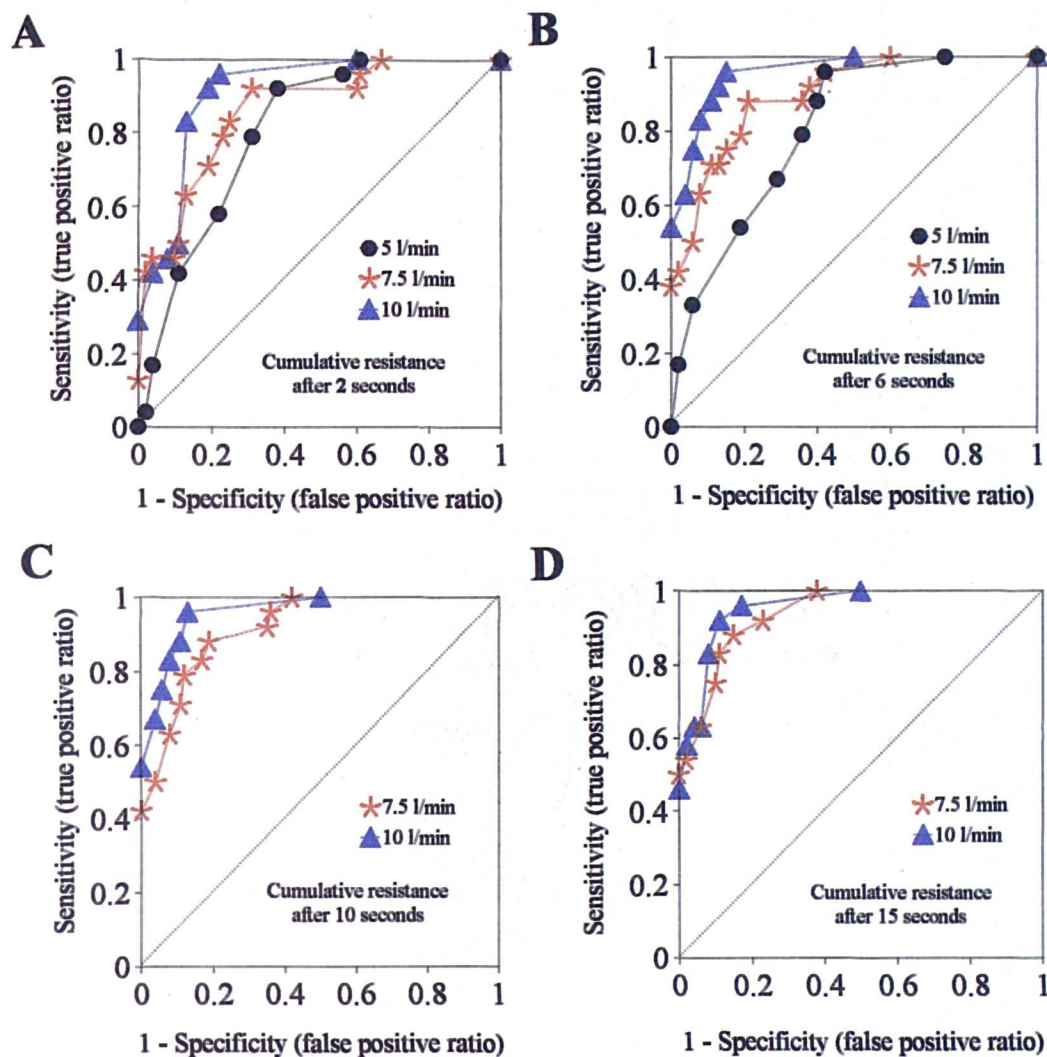


Figure 4.8 A-D ROC curves obtained for cumulative resistance readings obtained after 2, 6, 10 and 15 seconds respectively for the D_3 diagnostic threshold. A and B have three curves for readings taken with an airflow of 5, 7.5 and 10 l/min while C and D only have curves for readings taken at 7.5 and 10 l/min.

Table 4.1 A summary of optimum sensitivity and specificity values, respective cut-off values and the area under the ROC curves for different types of readings at the D₁ diagnostic threshold.

Type of reading	Airflow l/min	Optimum		Cut-off	Sens at Spec ≥ 93%/%	Cut-off	Area under ROC curve
		Sens/ %	Spec/ %				
Stable conductance	5	82	67	4.43	25	12.45	0.76
	7.5	61	96	1.74	61	1.00	0.80
	10	71	78	0.23	59	2.55	0.83
Cumulative resistance after 2 seconds	5	74	70	0.30/MΩ	31	0.16/MΩ	0.76
	7.5	76	89	1.90	63	1.45	0.90
	10	76	85	5.40	65	3.50	0.92
Cumulative resistance after 6 seconds	5	80	63	4.75	25	0.63	0.78
	7.5	84	74	67.10	61	20.40	0.87
	10	76	82	67.90	55	24.10	0.89
Cumulative resistance after 10 seconds	7.5	86	67	209.50	55	51.60	0.86
	10	74	85	154.00	59	60.70	0.89
Cumulative resistance after 15 seconds	7.5	86	67	409.50	59	153.60	0.87
	10	74	82	309.05	63	168.70	0.87

Table 4.2 A summary of optimum sensitivity and specificity values, respective cut-off values and the area under the ROC curves for different types of readings at the D₂ diagnostic threshold.

Type of reading	Airflow l/min	Optimum		Cut-off	Sens at Spec ≥ 93 %/ %	Cut-off	Area under ROC curve
		Sens/ %	Spec/ %				
Stable conductance	5	87	60	4.43	10	12.74	0.75
	7.5	74	95	1.74	74	1.74	0.86
	10	80	92	1.29	74	2.55	0.89
Cumulative resistance after 2 seconds	5	65	80	0.30/MQ	39	0.16/MQ	0.79
	7.5	85	81	1.90	8	0.21	0.89
	10	77	92	3.30	69	1.65	0.92
Cumulative resistance after 6 seconds	5	74	70	1.90	26	0.57	0.82
	7.5	69	92	17.00	59	13.30	0.88
	10	87	87	65.00	67	21.05	0.95
Cumulative resistance after 10 seconds	7.5	72	87	93.25	64	46.20	0.89
	10	87	87	152.60	74	60.70	0.93
Cumulative resistance after 15 seconds	7.5	72	95	147.90	72	147.90	0.91
	10	85	89	147.90	80	168.70	0.94

Table 4.3 A summary of optimum sensitivity and specificity values, respective cut-off values and the area under the ROC curves for different types of readings at the D_3 diagnostic threshold.

Type of reading	Airflow l/min	Optimum		Cut-off	Sens at Spec $\geq 93\%/ \%$	Cut-off	Area under ROC curve
		Sens/ %	Spec/ %				
Stable conductance	5	79	64	11.23	13	12.69	0.77
	7.5	92	87	2.24	58	5.28	0.89
	10	92	89	2.27	79	4.18	0.92
Cumulative resistance after 2 seconds	5	79	69	0.24/MQ	17	0.10/MQ	0.83
	7.5	83	75	1.45	46	0.33	0.89
	10	83	87	1.60	42	0.55	0.94
Cumulative resistance after 6 seconds	5	79	64	1.52	33	0.57	0.82
	7.5	83	83	16.70	50	4.50	0.90
	10	88	90	21.05	75	13.40	0.96
Cumulative resistance after 10 seconds	7.5	88	81	62.90	50	9.90	0.92
	10	96	87	96.87	75	24.80	0.97
Cumulative resistance after 15 seconds	7.5	88	85	125.30	63	37.14	0.95
	10	92	89	85.70	63	40.90	0.97

For each type of reading and level of caries diagnosis, the area under the ROC curve was always lower for readings taken with an airflow of 5 l/min, compared with those taken at 7.5 and 10 l/min. The lower area under the ROC curves for readings taken at 5 l/min was primarily due to low sensitivity values when the false positive ratio was kept small (specificity high). For this reason, readings taken at 5 l/min were not investigated any further. In each case, the area under the curve was lower for readings taken at 7.5 l/min than those taken at 10 l/min, however, the difference was generally small.

Figures 4.9 A and B show that the number of dentine lesions which gave cumulative resistance readings below the calculated lower 95% confidence limit of the sound sites increased with the time at which the reading was taken. When readings were taken at an airflow of 7.5 l/min, maximum discrimination between sound sites and those with dentine caries occurred at or after 15 seconds and at an airflow of 10 l/min at or after 13 seconds.

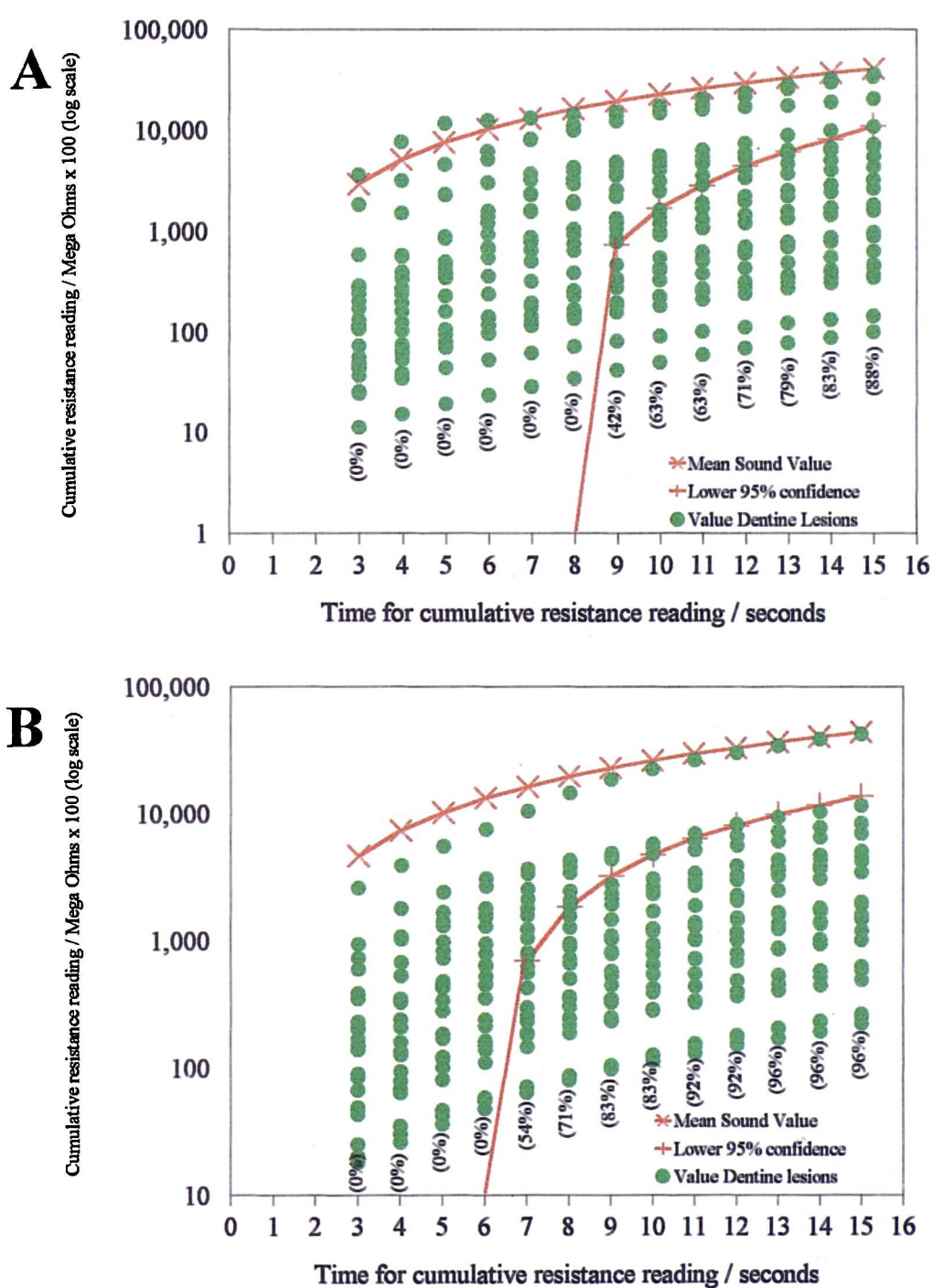


Figure 4.9 A&B The mean cumulative resistance and lower 95 % confidence limit for sound sites, together with the cumulative resistance value obtained for each dentine lesion, for readings taken at 7.5 l/min (A) and 10 l/min (B). The figures in parenthesis represents the proportion of dentine lesions with cumulative resistance values below the 95 % confidence limit for sound sites.

4.3.4 The relationship of stable conductance and cumulative resistance measurements with lesion depth and mineral loss.

Table 4.4 shows the Spearman correlation coefficients obtained when the various reading types taken at 7.5 l/min and 10 l/min were compared to the percentage mineral content in enamel and the measured depth of the lesion from the tooth surface, determined from the analysis of the macroradiographs. The correlation coefficients are presented for the whole sample, including dentine lesions, and for enamel lesions only. Correlation coefficients for dentine lesions only are also presented for the comparisons made between the various reading types and the percentage mineral content in dentine just beyond the EDJ, and the distance of the advancing front of the lesion from the EDJ. Table 4.4 only gives the results for cumulative resistance readings taken after 2, 6, 10 and 15 seconds, for full details of readings taken after 2, 4, 6, 8, 10, 12, 14, and 15 seconds see Appendix IV, page 248.

It can be seen that stable conductance readings gave moderate to strong correlation coefficients for the relationship with the percentage mineral content in enamel ($r = -0.67, p \leq 0.01$; $r = -0.68, p \leq 0.01$) and depth of lesion from the surface ($r = 0.64, p \leq 0.01$; $r = 0.66, p \leq 0.01$) for the whole sample at both 7.5 l/min and 10 l/min respectively. A moderate inverse relationship was obtained with the percentage mineral content in enamel lesions only ($r = -0.45, p \leq 0.05$) when an airflow of 7.5 l/min was used. Stable conductance readings taken at 7.5 l/min showed a moderate inverse relationship with the percentage mineral content in dentine lesions ($r = -0.46, p \leq 0.05$) and a moderate direct relationship with the depth of the dentine lesion from the EDJ ($r = 0.53, p \leq 0.01$). The corresponding relationships obtained for cumulative resistance

readings taken after 10 seconds were of the same order of magnitude but occasionally slightly stronger than obtained with the stable conductance readings.

Table 4.4 The relationship between reading type (demonstrated by Spearman correlation coefficients) and the percentage mineral content in enamel and the depth of the lesion measured from the surface of the tooth, for the whole sample and enamel lesions only. The relationship between readings and the percentage mineral content in dentine and the depth of lesion measured from the EDJ are also shown for dentine lesions only.

Reading type	Airflow l/min	Whole sample		Enamel lesions only		Dentine lesions only	
		% mineral in enamel	Lesion depth from surface	% mineral in enamel	Lesion depth from surface	% mineral in dentine	Lesion depth from EDJ
Stable conductance	7.5	-0.67**	0.64**	-0.45*	0.24	-0.46*	0.53**
	10	-0.68**	0.66**	-0.41	0.18	-0.40	0.54**
Cumulative resistance after 2 seconds	7.5	0.69**	-0.71**	0.07	0.08	0.60**	-0.64**
	10	0.75**	-0.73**	0.36	-0.01	0.56**	-0.68**
Cumulative resistance after 6 seconds	7.5	0.71**	-0.71**	0.27	-0.08	0.58**	-0.57**
	10	0.78**	-0.74**	0.53**	-0.23	0.43*	-0.56**
Cumulative resistance after 10 seconds	7.5	0.71**	-0.70**	0.35	-0.21	0.49*	-0.52**
	10	0.77**	-0.73**	0.58**	-0.26	0.39	-0.50**
Cumulative resistance after 15 seconds	7.5	0.71**	-0.71**	0.37	-0.26	0.44*	-0.49**
	10	0.76**	-0.72**	0.52**	-0.24	0.40*	-0.50**

** $P \leq 0.01$

* $P \leq 0.05$

4.3.5 Intra-examiner reproducibility.

Reproducibility was only assessed for stable conductance readings and cumulative resistance readings taken after 10s. Figure 4.10 A and B shows the difference between pairs of stable conductance readings plotted against the mean, for readings taken at an airflow of 7.5 and 10 l/min respectively. At 7.5 l/min the limits of agreement, or range within which a second reading would be expected to fall with a 95% confidence, were found to be +3.3 or -4.4 and at 10 l/min, +4.7 or -3.1. The intraclass correlation coefficient was 0.92 ($P < 0.01$) for readings taken at 7.5 l/min and 0.89 ($P < 0.01$) for those taken at 10 l/min. When the readings taken at 7.5 l/min were divided into dichotomous data using the optimum cut-off value for the D_1 and D_2 levels of diagnosis (1.74) an unweighted kappa value of 0.92 was obtained. An unweighted kappa value of 0.92 was also obtained when the optimum cut-off for the D_3 level of diagnosis was used (2.24). Similarly for readings taken at 10 l/min and split into dichotomous data according to the cut-off value for the D_1 level of diagnosis (0.23) an unweighted kappa value of 0.69 was obtained, when split for D_2 level of diagnosis (1.29) the kappa value was 0.76 and when split for the D_3 level of diagnosis (2.27) the kappa value was 0.85.

Figure 4.11 A and B shows the difference between pairs of cumulative resistance readings taken after 10 seconds plotted against the mean, for readings taken at an airflow of 7.5 and 10 l/min respectively. The limits of agreement for readings taken at 7.5 l/min were +170 M Ω and -198 M Ω and for readings taken at 10 l/min, +134 M Ω and -196 M Ω . It is evident from the Figures that the difference in readings taken on separate occasions was larger with higher readings. To investigate this apparent affect a randomly chosen cut-off of 93.25 M Ω was used to divide the data according to the original readings taken at 7.5

l/min. The limits of agreement were then calculated for readings below (total number = 12) and above this figure (total number = 15). The limits of agreement for the larger figures was +195 MΩ and -169 MΩ, and for the lower figures +143 MΩ and -215 MΩ. Similarly, for readings taken at 10 l/min when the data was split according to whether the original reading was above or below 109.05 MΩ the limits of agreement were +176 MΩ and -213 MΩ for the higher figures (total number = 12) and +101 MΩ and -183 MΩ for the smaller figures (total number = 15).

The intraclass correlation coefficient for the cumulative resistance readings taken after 10 seconds and at an airflow of 7.5 l/min was 0.68 ($p \leq 0.01$) and for those readings taken at 10 l/min was 0.77 ($p \leq 0.01$). Kappa values for cumulative resistance readings taken after 10 seconds and at an airflow of 7.5 l/min were calculated when the readings were split into dichotomous data according to the relevant optimum cut-off points for the three levels of caries diagnosis; D₁ (cut-off 209.50 MΩ) kappa value 0.42, D₂ (cut-off 93.25 MΩ) kappa value 0.78 and D₃ (cut-off 62.90 MΩ) kappa value 0.62. Similarly for cumulative resistance readings taken after 10 seconds and at an airflow of 10 l/min, using the D₁ cut-off (154.0 MΩ) the kappa value was 0.52, using the D₂ cut-off (152.6 MΩ) the kappa value was 0.63 and using the D₃ cut-off (96.87 MΩ) the kappa value was 0.64.

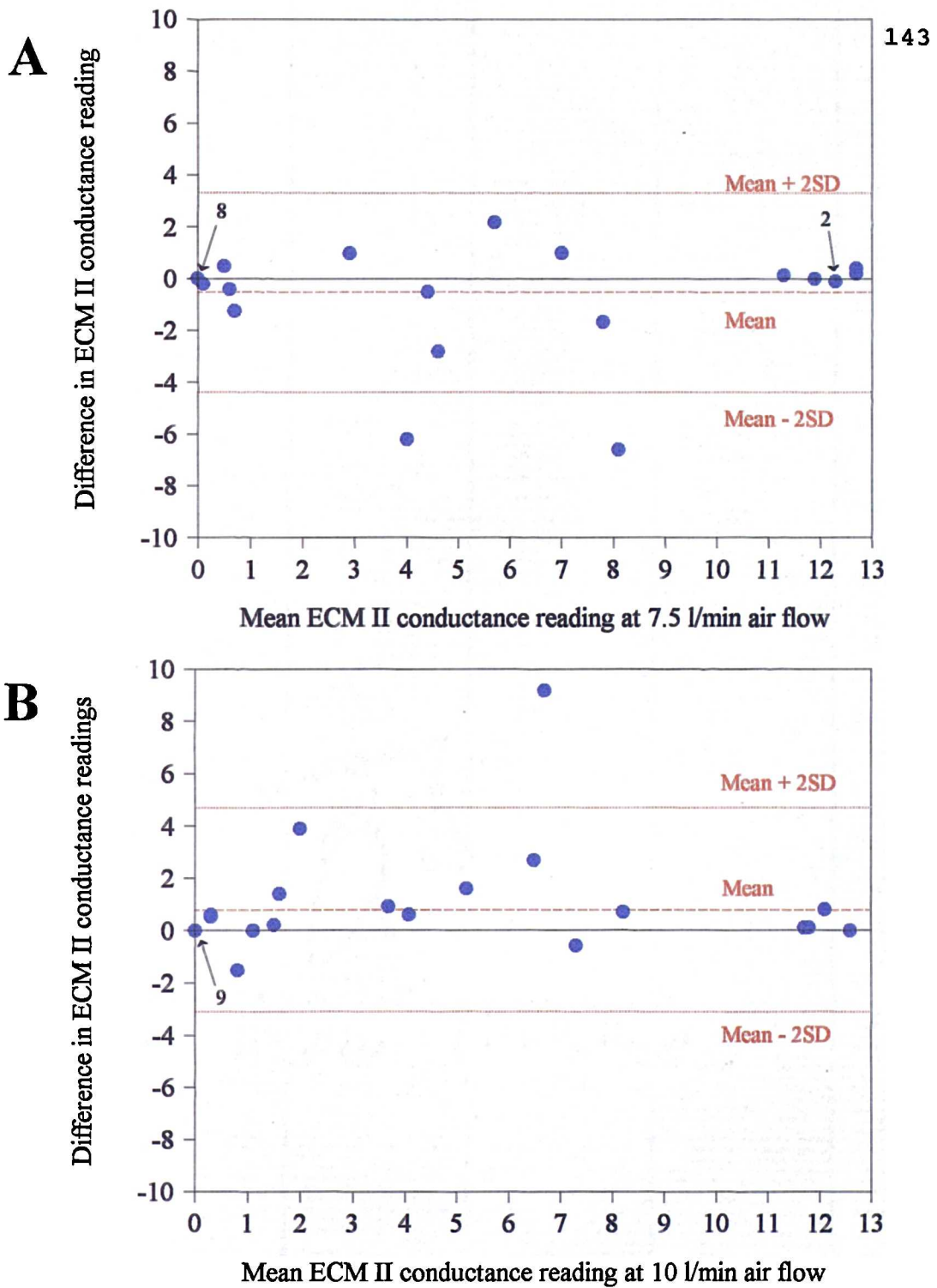


Figure 4.10 A&B A plot of the mean of, and the difference between, paired stable conductance readings taken of the same investigation site for readings taken at 7.5 l/min (A) and 10 l/min (B). The mean of the differences, and the upper and lower limits of agreement are shown.

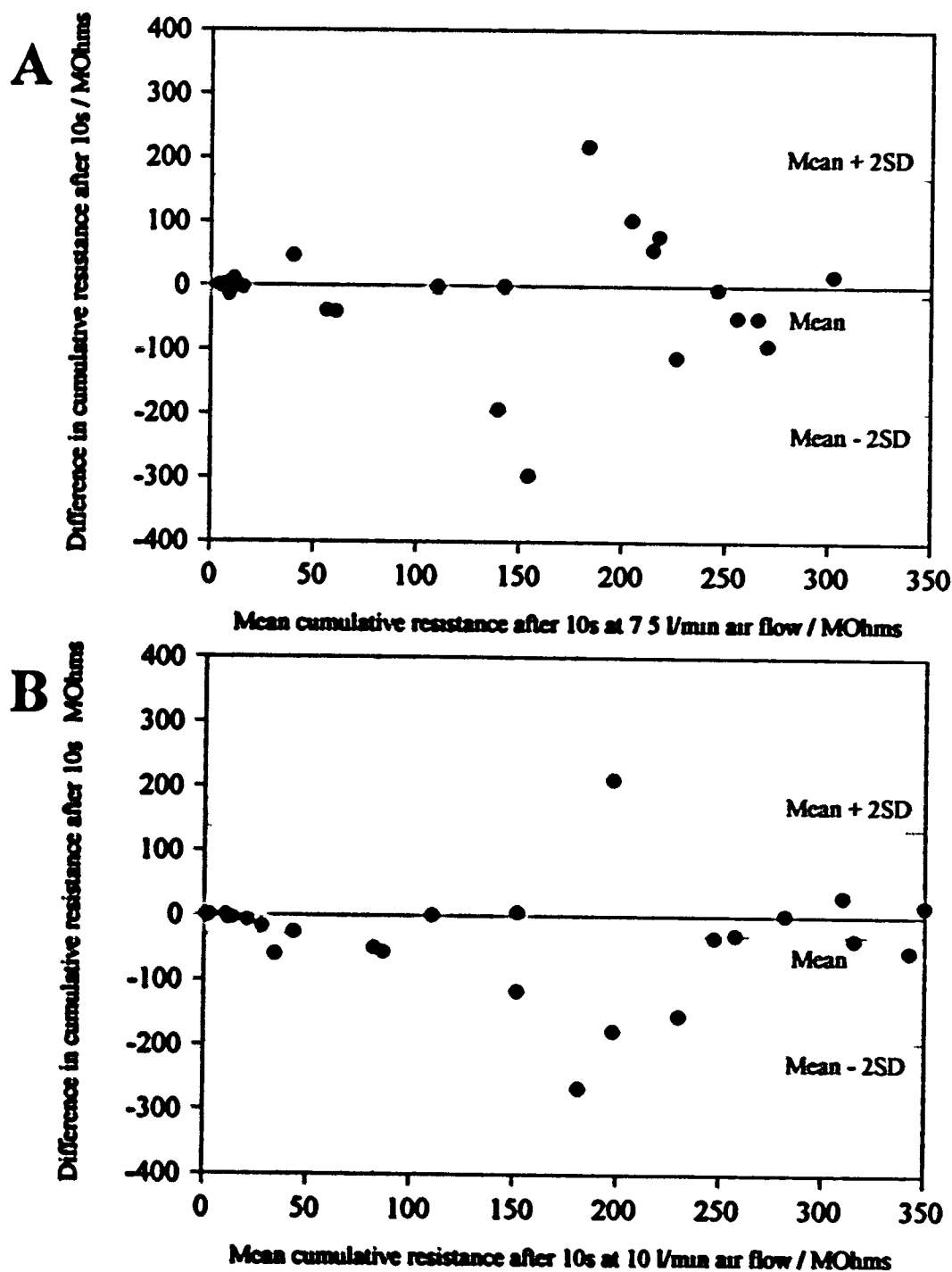


Figure 4.11 A&B A plot of the mean of, and the difference between, paired cumulative resistance readings taken after 10 seconds of the same investigation site for readings taken at 7.5 l/min (A) and 10 l/min (B). The mean of the differences, and the upper and lower limits of agreement are shown.

4.4

Discussion.

4.4.1 Calibration of the ECM II.

The new ECM II prototype used in this study had a continuous, expanded scale giving readings to two decimal places up to 13.25. The calculation of a mean resistance value for each whole conductance reading on the ECM II was only for comparison with the Vanguard electronic caries detector. Calibration of the ECM II against a physical model (variable standard resistor) produced similar results to the Vanguard electronic caries detector (Figure 4 3 A). Both machines possess a logarithmic relationship between conductance readings and measured resistance. Although the minimum, maximum and calculated mean resistance value that corresponded to each whole conductance reading on each machine were different, there was considerable overlap in the range of resistance for each reading. This makes comparisons between machines possible.

4.4.2 The relevance of airflow to stable conductance and cumulative resistance measurements.

The use of airflow to and around the ECM II probe tip is essential for site specific readings. Airflow is necessary to break the film of saliva covering the tooth so that in clinical use conduction of current to the gingival margin and adjacent sites of the fissure is prevented. Airflow also ensures that the area of contact directly beneath the probe tip is standardised. A pool of saliva within the fissure will effectively increase the area of contact between the probe and the tooth, and area of contact has been shown to influence resistance values (Hoppenbrouwers *et al.*, 1986). However, once the salivary film on the tooth is removed, continued airflow produces a dynamic situation in which the tooth tissue

is subjected to continued dehydration, causing resistance to rise or conductance to fall.

With continued airflow, the rate at which the tooth dries out will depend upon its carious state. At one extreme, a sound fissure whose enamel contains relatively little fluid will give a high resistance rapidly; the initial low resistance being due to surface conduction (Figure 4.4). At the other extreme, a large dentine lesion beneath a non-cavitated enamel lesion will act as a reservoir of moisture, itself being hydrated by the dental pulp. The resistance in this example (Figure 4.4) remains low despite continued airflow because the enamel is hydrated from the dentine lesion reservoir at the same rate as moisture is lost from the tooth surface. The resistance of a tooth with an enamel lesion will depend upon the size of the lesion in terms of depth and mineral loss, and hence on the amount of moisture it can absorb. Frequently, once the surface moisture has been removed, the resistance rises slightly and stabilises for 2-3 seconds, probably as the moisture is gradually lost from the body of the enamel lesion. A second rapid rise in resistance then occurs due to the fact that lesion dehydration is greater than rehydration from the pulp-dentine complex. Thus it can be seen that the resistance measurements depend on the rate of lesion dehydration, which will be a function of the amount of airflow, and rehydration from the pulp-dentine complex.

It is possible that two enamel lesions, differing in depth and porosity, could dry out at different rates but still have a final stable conductance of 0 because neither lesion gave resistance values that corresponded to the same whole conductance value for three consecutive seconds. By adding the resistance values obtained at 1 second intervals to obtain a cumulative resistance value, an overall drying out profile can be obtained. To

investigate whether cumulative resistance values or stable conduction values were optimal for electronic caries diagnosis ROC curves were constructed. These curves were also used to investigate the effect of airflow on both types of reading.

4.4.3 Interpretation of the ROC curves.

The area under the ROC curve is thought to provide a single quantitative index of accuracy of a diagnostic system (Hanley and McNeil, 1982). An area of 0.5 represents no accuracy while an area of 1 represents perfect accuracy. In order to detect statistically significant differences between the areas under two ROC curves, the standard error of the areas under the fitted smooth curves are required. To complicate matters, when ROC curves are generated using the same sample, the areas are likely to be correlated for different diagnostic tests. That is, "if the vagaries of random sampling" produce higher/lower than expected accuracy index for one diagnostic test, because the sample consisted of a larger than usual number of easy/difficult to diagnose lesions, then the accuracy of the second diagnostic test will probably also be correspondingly higher/lower than expected (Hanley and McNeil, 1983). Thus to complicate the statistical approach further, an estimate of the correlation between areas under two ROC curves is necessary. Although statistical computer programs are available to carry out these tests, they were not applied in this study because of the aforementioned complications. Instead only the location of the curves and the graphical calculation of the area under them were used to assess the accuracy of each diagnostic procedure.

It is possible that two ROC curves could have the same area but different configurations, thus the optimum sensitivity and specificity values (designated by the point closest to the

top left corner of the graph) and the sensitivity when the specificity was greater than 93% were thought to be more important measures of diagnostic performance of the various measurements. A specificity of 93% was chosen in this analysis because it was felt that false positive diagnoses should be kept to a minimum, particularly if the information were to lead to operative treatment. The 93% figure was chosen for convenience due to calculations made on the numbers in each sound and carious group.

4.4.4 The effect of airflow on stable conductance and cumulative resistance measurements.

Little difference was found between the ROC curves generated for stable conductance readings taken at an airflow of 7.5 l/min and 10 l/min, a finding also found for cumulative resistance measurements after all time intervals. However, all readings taken at an airflow of 10 l/min led to a slightly, but consistently better diagnostic performance than those taken at 7.5 l/min. Of more importance however, is that all measurements taken at an airflow of 5 l/min resulted in unacceptably low sensitivity values when the specificity was maintained above 93%. This is probably due to the fact that at such a low airflow the elimination of surface moisture is delayed to such a degree that problems associated with short circuiting of current to the gingival margin and adjacent areas of the fissure prevents discrimination between sound and carious sites.

4.4.5 Stable conductance or cumulative resistance measurements?

It is generally accepted that fissure sealants, sealant restorations and amalgam or composite restorations last for a finite duration, and that replacement of sealant restorations and conventional restorations is associated with further tooth loss. It is

important therefore that any new diagnostic technique should have a high specificity so that sound sites are not inadvertently diagnosed as carious and treated operatively. In contrast, however, a "wait and watch" approach to pit and fissure caries has been described by Elderton (1985) as "fraught with danger" due to the difficulty in assessing its status. Thus the point at which caries has involved the dentine may be regarded as an optimum point for operative intervention. Figure 4.9 A and B shows that for cumulative resistance readings the important discrimination between sound sites and sites with dentine caries occurs after 15 seconds for readings taken at 7.5 l/min and after 13 seconds for readings taken with an airflow of 10 l/min. After these times 88% and 96% of dentine lesions gave readings below the calculated lower 95% confidence limit for sound readings when an airflow of 7.5 l/min and 10 l/min respectively were used. Thus the higher airflow was better for such discrimination.

Cumulative resistance values after 10 seconds produced clinically acceptable sensitivity values when a specificity of 93% or more were set as a prerequisite. Readings taken at an airflow of 7.5 l/min gave sensitivity values of 55% for the D_1 diagnostic threshold, 64% for the D_2 diagnostic threshold and 50% for the D_3 threshold (Tables 4.1 - 4.3). The corresponding cumulative resistance values taken at an airflow of 10 l/min, gave higher sensitivities at each level of caries diagnosis (D_1 = 59%; D_2 = 74%; D_3 = 75%).

When cumulative resistance readings taken after 10 seconds were compared to stable conductance measurements, it was found that at 7.5 l/min the stable conductance measurements performed better overall, and at 10 l/min little difference was found between the two types of reading. In addition, the overall performance of stable

conductance measurements taken at either 7.5 or 10 l/min was good. Compared with the results obtained *in vitro* with the Vanguard and presented in Chapter 2 (Table 2.3), the ECM II used with an airflow of 7.5 l/min resulted in improved specificity at both the D₁ and D₂ threshold. The optimum sensitivity and specificity for the ECM II was 61% and 96% for the D₁ diagnostic threshold (Table 4.1) and 92% and 87% for the D₂ threshold (Table 4.3); the corresponding Vanguard results were 75% and 83% at the D₁ threshold and 93% and 63% at the D₂ threshold (Table 2.3). It would therefore appear that the basic theory behind the Vanguard was optimal for caries diagnosis, and that regulation and quantification of airflow could improve the technique by reducing the number of false positive diagnoses.

4.4.6 The relationship of stable conductance and cumulative resistance measurements with lesion depth and mineral loss.

Using the expanded, continuous stable conductance scale at an airflow of 7.5 l/min a moderate to strong, negative correlation with the mineral content in enamel ($r = -0.67$, $p \leq 0.01$) and a moderate to strong, positive correlation with depth of lesion from the surface ($r = 0.64$, $p \leq 0.01$), was found for the whole sample (Table 4.4). That is, as the mineral content in enamel fell and the depth of lesion increased, the conductance increased. These results were in agreement with those obtained for the whole sample investigated in Chapter 3.

When enamel lesions only were considered, a moderate negative correlation was found between stable conductance readings and percentage mineral content in enamel ($r = -0.45$, $p \leq 0.05$), however, no relationship was found with the lesion depth measured

from the surface. Thus, for enamel lesions at least, the conclusions of the previous chapter that mineral loss in enamel was more relevant to resistance values than lesion depth would appear to hold true. This may be because when enamel caries is present the whole thickness of enamel may be affected to a certain degree and the idea of a well defined circumscribed lesion may be too simplistic. The weaker relationship between stable conductance readings and mineral content in enamel lesions means that monitoring small changes in the degree of mineralisation may be difficult.

Similarly, when only dentine lesions were considered, a moderate negative correlation was found between the stable conductance readings taken with an airflow of 7.5 l/min and the percentage mineral content in dentine ($r = -0.46$, $p \leq 0.05$). In addition, a positive direct relationship was found between stable conductance readings and the depth of the lesion measured from the EDJ ($r = 0.53$, $p \leq 0.01$). Thus the modifications made to the ECM II, namely the provision of a continuous and extended stable conductance scale to 13 25, which corresponds to low resistance values, would appear to enable the progress of dentine lesions to be monitored.

The correlation coefficients obtained for enamel lesions only and dentine lesions only, with percentage mineral content and lesion depth were moderate. Thus the ability to monitor changes in lesion severity in enamel only or dentine only, although possible, is limited. However, it is important to visualise the whole disease process from a sound tooth to deep dentine caries and when this was done in this study by analysing the results for the whole sample, the relationships discussed above were stronger, making monitoring of the overall disease process possible.

The relationships and correlation coefficients discussed above, for stable conductance readings taken with an airflow of 7.5 l/min, were of the same order of magnitude as those taken at 10 l/min and when cumulative resistance measurements were taken after 10 seconds. Attention has been drawn previously to the fact that resistance and conductance have a reciprocal relationship. Thus, the sign of the correlation coefficients obtained with stable conductance measurements are the reverse of those obtained with cumulative resistance measurements. For example, the cumulative resistance decreases with increased lesion depth (negative correlation) whereas the stable conductance reading increases with increased lesion depth (positive correlation).

4.4.7 Intra-examiner reproducibility.

Intra-examiner reproducibility is important in any diagnostic technique. Electronic resistance measurements should be comparable when repeated otherwise poor reproducibility could be confused with changes as a result of demineralisation or remineralisation. Reproducibility may be of particular importance if the change in reading would lead to operative treatment.

In considering the reproducibility of the readings taken in this study the limits of agreement were calculated between which 95% of readings would fall if repeated. However, to show whether this error would lead to a dentist changing from non-operative to operative treatment the results were divided into dichotomous data according to the optimum cut-off values for the D_1 , D_2 and D_3 diagnostic thresholds and kappa statistics applied. When this was done, the reproducibility of stable conductance readings was better for readings taken at 7.5 l/min than at 10 l/min. The limits of agreement calculated

for the stable conductance readings taken at 7.5 l/min means that they can be expected to vary by +3.3 or -4.4. These figures appear high when compared to the overall conductance scale (-0.45 - 13.25) however, this rarely led to readings changing from one side of the cut-off value to the other, thus, the kappa values were excellent (0.92).

In this study many factors have been taken into consideration to assess various reading types, taken at different airflows. Whilst one type of reading may lead to an improvement in sensitivity, it may lead to an unacceptable reproducibility. Importance has been placed on maintaining a high specificity and achieving a high level of reproducibility. These were best achieved by stable conductance readings taken with an airflow of 7.5 l/min. However, in general, the differences obtained with different reading types taken at 7.5 l/min and 10 l/min were small with a trend overall for slightly better results at the higher airflow. The final electronic caries meter to be marketed should ideally be free standing with its own air supply independent from the dental unit. Such a portable unit would allow use in epidemiological studies and convenient movement between surgeries. However, this would necessitate a battery generated air supply which is unlikely to achieve the air pressure required to generate an airflow of 10 l/min. Thus an airflow of 7.5 l/min is also a more realistic alternative which needs further investigation.

4.5**Conclusions.**

The conclusions that can be drawn from this study are:

1. The ECM II stable conductance readings are broadly comparable to the Vanguard readings. Both are logarithmically related to resistance, with the ECM II having a continuous, extended scale.
2. Airflow is highly relevant to conductance and resistance measurements, and a minimum of 7.5 l/min is required.
3. The optimum time to take a reading would appear to be that for the stable conductance reading or a cumulative resistance reading after 10 seconds.
4. The relationships between stable conductance readings and cumulative resistance readings with the mineral content in enamel and the lesion depth from the surface make monitoring of the carious process possible with objective measurements.
5. The reproducibility of the stable conductance readings was found to be better than cumulative resistance measurements at or over 10 seconds. Thus stable conductance readings, taken at an airflow of 7.5 l/min would seem optimal for the diagnosis and monitoring of occlusal caries. However, the error made in repeating a reading, means that relatively large changes in resistance are required to confirm true lesion progression.

CHAPTER 5:
A COMPARISON OF VISUAL, FIBRE OPTIC TRANSILLUMINATION,
RADIOGRAPHIC AND ELECTRONIC METHODS OF OCCLUSAL
CARIES DIAGNOSIS IN MOLARS AND PREMOLARS.

5.1 Introduction.

So far, all investigations have been conducted by the author. However, dentists disagree in their treatment planning decisions (Elderton & Nuttall, 1983) and a possible source of this inconsistency may lie in differences in the diagnosis of lesions in pits and fissures (Slack, 1958). Rytömaa *et al.* (1979) have shown that this disagreement may be carried over into plans for treatment, which can lead to a nine-fold difference in the number of teeth treated for the same patient. Therefore, not only does a diagnostic system have to be easy to use and accurate, it must demonstrate good reproducibility between examiners (inter-examiner), and for the same examiner on different occasions (intra-examiner). In addition, any new system must show advantages over older methods if it is to be accepted by the dental profession.

The present study had the following aims:

1. To compare visual, fibre optic transillumination (FOTI), radiographic and electronic methods of occlusal caries diagnosis.
2. To assess the intra-examiner reproducibility of the above techniques.
3. To assess the inter-examiner variation of the above techniques.

5.2

Materials and method.

5.2.1 Selection of teeth and preparation for radiography.

Ninety six freshly extracted premolar (48) and molar (48) teeth, with no existing restorations were selected with a range of carious appearances of the occlusal surfaces varying from apparently sound to frank cavitation. The teeth were cleaned and stored in saline to which a few crystals of thymol were added to inhibit further bacterial activity. Each tooth was removed from the saline and the occlusal surface examined visually by the author. If the surface appeared unblemished, it was classified as sound. For those surfaces whose appearance was altered in some way, the worst affected site was determined and classified either as:

- Stained fissure.
- White spot lesion at entrance to fissure.
- Brown spot lesion at entrance to fissure.
- Undermining stain shining up through intact enamel.
- Cavitation <0.7mm or >0.7mm (determined with a blunt-ended probe).

A plan of the occlusal surface was drawn and the site which appeared most likely to be carious visually and could be located reproducibly with a probe, was selected and recorded on the plan.

The teeth were positioned in acrylic arch trays to simulate a normal anatomical relationship. The roots of the teeth were then invested in die stone to a depth

corresponding to a healthy bone level and pink wax (Anutex Dental Modelling Wax. Assoc. Dental Products Ltd. Swindon, Berks, U.K.) was placed and contoured to simulate healthy gingiva. The arches were then mounted in an articulator. Six pairs of jaws were prepared with first and second premolar and molar teeth in each quadrant (Figure 5.1).

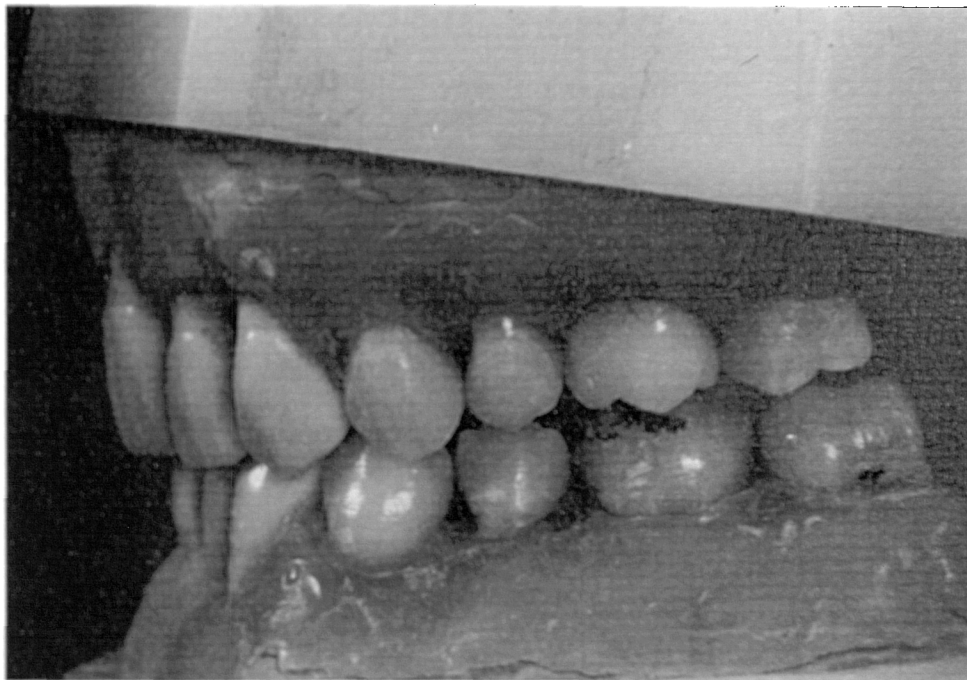


Figure 5.1 Teeth mounted in an articulator.

5.2.2 Radiographic technique.

Bitewing radiographs were taken using a Benn Bitewing Film Holder (Benn Research Ltd. Stanmore, Middlesex.). A 16mm thick disc of dental modelling wax was attached to the aiming ring of the film holder to simulate the soft tissue of the patient's cheek (Figure 5.2). Use of this holder, according to the manufacturer's instructions, enabled reproducible positioning of the film packets and X-ray tube head, in relation to the teeth, while bitewing radiographs were exposed. The radiographic films used in this study were Agfa D-speed and Agfa E-speed film. The X-ray source was provided by a General

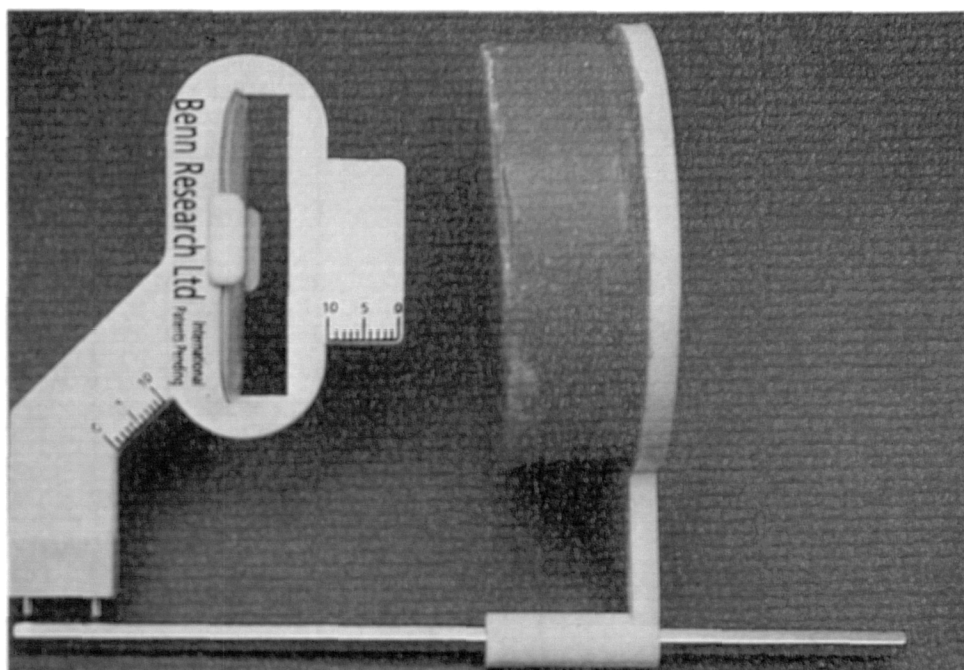


Figure 5.2 Soft tissue equivalent material attached to the aiming ring of the Benn Bitewing Film Holder.

Electric GE 1000 intraoral X-ray system using an eight inch long open cone (General Electric, Medical Systems Ltd., Slough, Berkshire) and filtration of the primary beam by 2.55mm aluminium. The peak kilovoltage (kVp) of the machine was set at 65kVp, the milliamperage (mA) at 15 mA and the D-speed films were exposed for 0.25 seconds and the E-speed films for 0.12 seconds. All the films were exposed on the same day and automatically developed within one hour. The developer used was a Dentomat P10 (Hope Industries Inc. Lechworth Garden City, Herts) with Kodak RP X-o-mat developer and fixer (Kodak, Hemel Hempstead, Herts). The optical density of all processed radiographic films was checked with a densitometer at specific sound dentine sites to ensure all the films were comparable and consistent with each other. The reproducibility of film packet, teeth and X-ray beam orientation achieved for D- and E-speed films taken of the same

teeth was assessed subjectively by the author in conjunction with one of the radiologists who took part in this study. Particular attention was paid to the distance between the teeth, cuspal superimposition and the borders of the film with respect to missing parts of teeth. Care was taken to avoid any proximal overlap.

5.2.3 Visual and FOTI examination.

The pairs of arches were subsequently transferred to a phantom head, to which a face mask, made from addition cured silicone impression putty, was attached. This simulated the soft tissues of the cheeks and lips, which normally shadow the teeth *in vivo*.

Five examiners were chosen for this study; two worked in the Dental Radiology Department at UMDS, two were part-time general dental practitioners and one was a university teacher of conservative dentistry. Each examiner was asked to examine visually the occlusal aspect of each tooth and record the surface as follows:

- sound,
- caries into enamel only,
- caries into dentine,
- caries into pulp.

The use of a probe was not allowed, but a three-in-one syringe was provided to dry the teeth.

On a separate occasion, the teeth were examined with a fibre optic light. The light source was provided by a Bioptics, high intensity light output and the fibre optic tip was 0.5mm in diameter (Figure 5.3). For this examination the operating light was turned off but the

room lights remained on. Each examiner was asked to record each occlusal surface using the same categories as for visual examination alone. None of the examiners used FOTI in routine practice and no training was provided for this study.

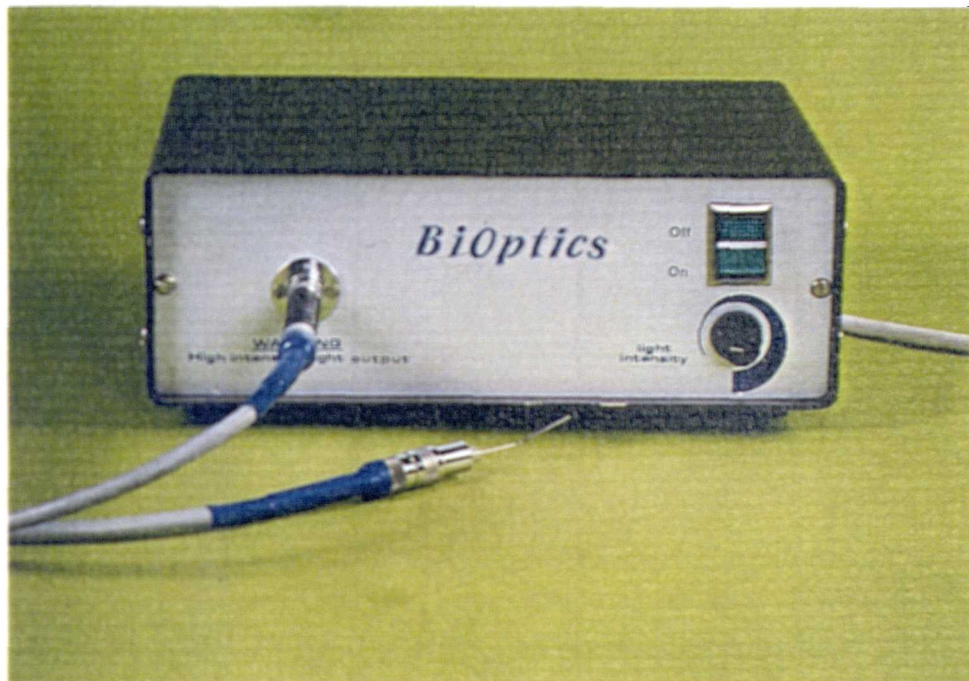


Figure 5.3 BiOptics high intensity light source and fibre optic tip.

5.2.4 Examination of the radiographic films.

All radiographs were viewed under ideal conditions, that is on a viewing box with extraneous light masked by black card and no room lighting, as described by Wuehrmann (1970). Each examiner randomly viewed the films at two separate sittings to reduce examiner fatigue. For every radiograph, the examiner scored each occlusal surface as follows:

- sound,
- radiolucency confined to the outer 1/2 of enamel,
- radiolucency in the pulpal 1/2 of enamel,
- radiolucency in the outer 1/2 dentine or
- radiolucency through to the pulpal 1/2 dentine.

5.2.5 Stable conductance measurement.

Following visual, FOTI and radiographic examinations the teeth were removed from the arches, cleaned of stone and wax and immersed in saline to rehydrate. Each examiner was informed how to use the ECM II and supervised by the author for a small number of trial readings. The readings were made as described in Chapter 4 for stable conductance readings using an airflow of 7.5 l/min. Readings were taken at the site determined by the author as most likely to be carious.

5.2.6 Intra-examiner reproducibility.

Two pairs of arches (one third of the teeth) were selected for re-examination. Intra-examiner reproducibility was assessed by asking the examiners to repeat each of the examination techniques for these arches. To reduce the risk of examiner bias, at least a week was allowed to elapse before re-examination.

5.2.7 Histological validation.

Following all the examinations, the teeth were serially sectioned in a mesio-distal direction to produce 4 to 6 sections per tooth of approximately 0.6 - 1.0 mm thickness. Both sides of each section were examined by the author, who was not involved in the

other examinations of the teeth, using x3 magnification. The histological appearance of the occlusal surface was recorded as:

- Sound,
- Caries confined to outer ½ of enamel,
- Caries to pulpal ½ of enamel,
- Caries to the outer ½ of dentine,
- Caries to the pulpal ½ of dentine.

For every tooth, the appearance of each side of each section varied from the subsequent section face. The greatest recorded depth from the multiple sections of each tooth served as the "overall gold standard" for validation of the examiners' decisions. However, the ECM II recorded site specific readings for the area directly beneath the probe tip and the appearance of the corresponding section served as the "site specific gold standard". Both gold standards were used in the validation of the ECM II. The reproducibility of the author in the histological assessment of the sections was checked by re-examination of the same two pairs of arches used in the analysis of the reproducibility of the examination techniques.

5.2.8 Statistical analysis.

Statistical analysis was carried out separately for premolars and molars. The sensitivity and specificity achieved with each examination technique was calculated for each examiner at the D_1 and D_2 diagnostic thresholds described and used in Chapters 2 (page 76) and 3 (page 101). For the analyses of ECM II readings, the stable conductance values

determined in Chapter 4 which gave optimum sensitivity and specificity were used; values below and including which were taken to represent a sound site. Analysis of variance was used to assess which factors influenced the sensitivity and specificity values obtained for both the D₁ and D₂ diagnostic threshold. The factors investigated were tooth type (molar or premolar), examiner and examination technique. Post analysis of variance contrast was used to investigate whether the ECM II resulted in significantly higher sensitivity and specificity values, compared to the other diagnostic techniques. The intra-examiner reproducibility for each technique was assessed by calculating the percentage agreement of observations or readings made at first and second examination. The same procedure was used to assess the reproducibility of the histological validating technique. Inter-examiner variation was assessed by calculating the mean and standard deviation for sensitivity and specificity values obtained for each diagnostic technique at both diagnostic thresholds. The coefficient of variation was then calculated by dividing the standard deviation by the mean and expressing the resultant proportion as a percentage. The higher the percentage the larger the variation between examiners.

5.3

Results.

The visual examination of the occlusal surface made by the author revealed that 11 (23%) of the molar teeth appeared sound, 17 (35%) had stained fissures, 16 (33%) had white or brown spot lesions, 3 (6%) had undermining stain of the dentine shining up through apparently intact enamel and only 1 (2%) had a cavity (>0.7mm in diameter) as the predominant feature. The corresponding distribution of sites for premolars according to visual appearance were, 17 (35%) sound, 25 (52%) stained, 5 (10%) white or brown spot

lesions, 1 (2%) undermining stain and none were cavitated.

The overall gold standard, that is the deepest recorded depth of a lesion for a single tooth, judged from the multiple sections, resulted in a lower number of sound recordings and a higher number of dentine and deep dentine lesions compared to the site specific gold standard, where the ECM II readings were taken (Figure 5.4). This was true for both molars and premolars. Thus the initial visual examination of the whole teeth by the author failed to identify the worst affected site in all the teeth.

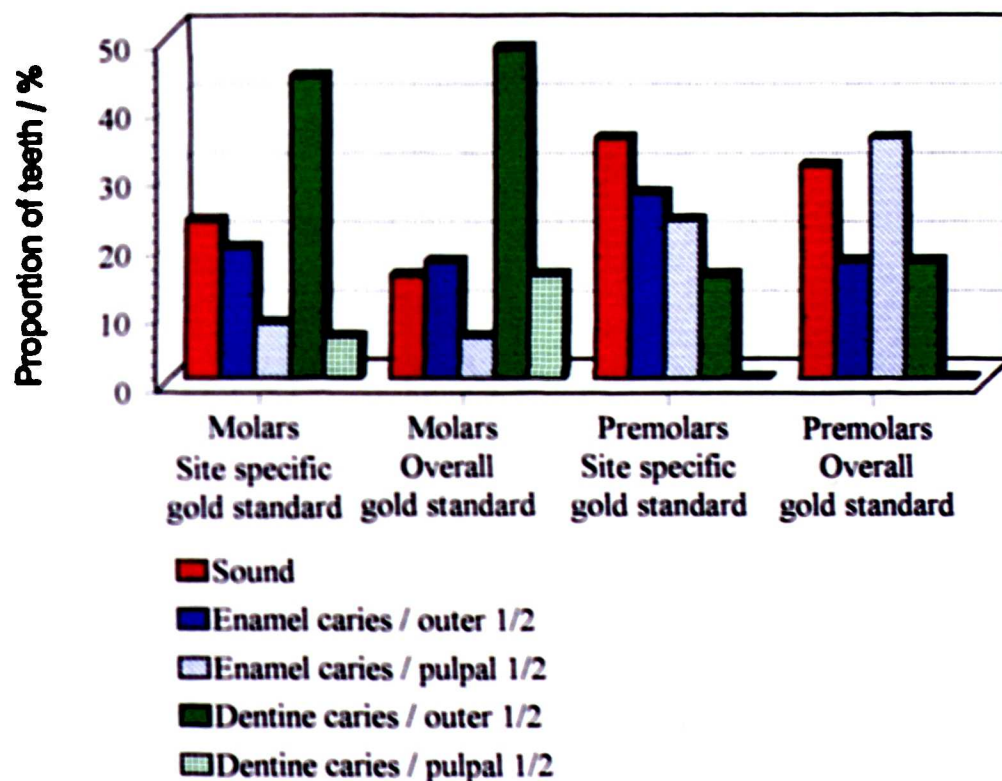


Figure 5.4 Percentage frequency distribution of investigation sites, according to the site-specific and overall gold standard, for molars and premolars.

Of the 96 teeth investigated in this study 19 (20%) showed a discrepancy between the "site specific gold standard" and the "overall gold standard". In 6 the "site specific gold standard" was sound, but 3 had an enamel lesion and 3 a dentine lesion at an adjacent site. Nine teeth had a "site specific gold standard" of caries in enamel (7 of which were confined to the outer half) of which 4 recorded dentine caries as the "overall gold standard". Five teeth showed a discrepancy of lesion depth from the outer to pulpal half of enamel and 4 from the outer to pulpal half of dentine when the two gold standards were compared.

5.3.1 Comparison of diagnostic techniques.

Figure 5.5 A - D shows the mean sensitivity and specificity for each diagnostic technique for molars (A & B) and premolars (C & D) at the D_1 (A & C) and D_2 (B & D) diagnostic thresholds. The actual values obtained for each examiner can be seen in Tables 5.1 and 5.2. The sensitivity values obtained with the ECM II were higher than the corresponding values obtained with any other diagnostic technique. However, all sensitivity values obtained when examining premolars were lower than those obtained for molars.

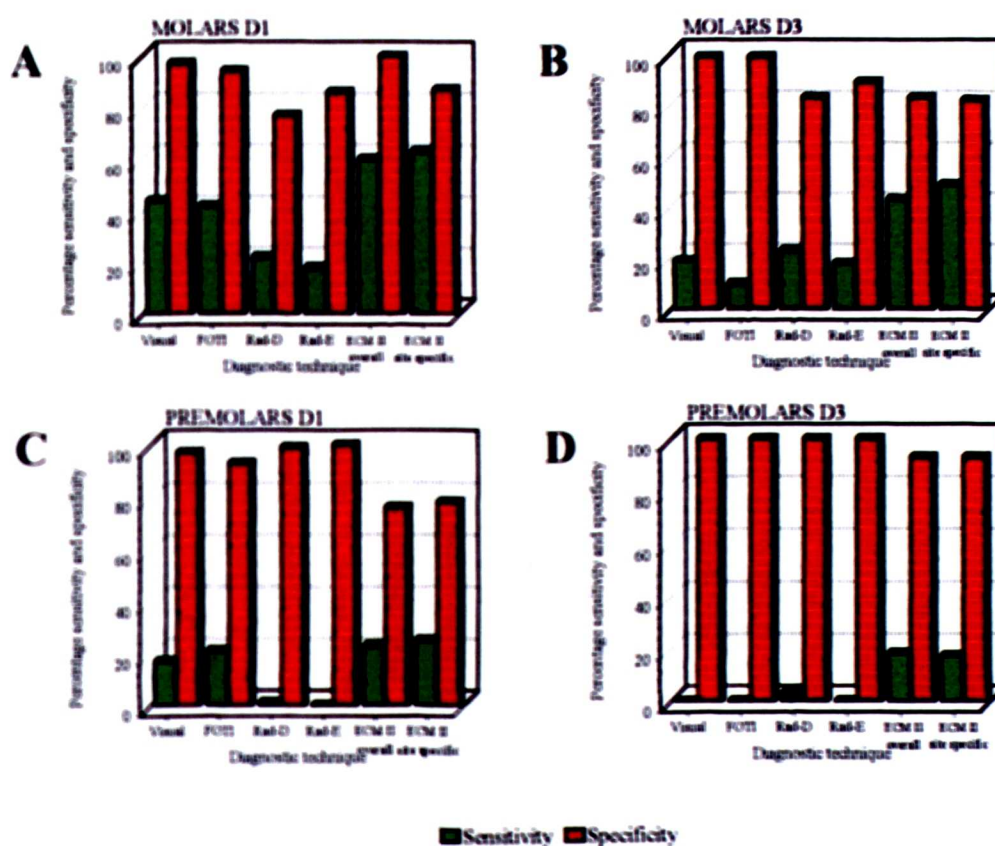


Figure 5.5 The mean sensitivity and specificity values for each diagnostic technique at the D₁ (A and C) and D₃ (B and D) diagnostic threshold, for molars (A and B) and premolars (C and D). Note the ECM II has been validated against the site specific gold standard and overall gold standard.

Table 5.1 The sensitivity and specificity values obtained for five examiners and five diagnostic techniques for the diagnosis of occlusal caries in 48 molars only. The mean sensitivity and specificity for each diagnostic technique is also presented.

Examination technique		Diagnostic Threshold	Examiner					Mean
			1	2	3	4	5	
Visual	Sensitivity %	D ₁	61	56	34	29	42	44
		D ₂	17	39	87	28	28	19
	Specificity %	D ₁	86	100	100	100	100	97
		D ₂	100	94	100	100	100	99
FOOT	Sensitivity %	D ₁	71	44	31	27	37	42
		D ₂	13	13	87	87	18	18
	Specificity %	D ₁	86	100	100	86	100	94
		D ₂	100	100	100	94	100	99
Radiographic D-speed	Sensitivity %	D ₁	18	44	15	12	29	22
		D ₂	13	43	17	13	38	23
	Specificity %	D ₁	71	57	86	100	71	77
		D ₂	89	56	94	100	78	83
Radiographic B-speed	Sensitivity %	D ₁	18	32	18	12	24	18
		D ₂	13	38	18	13	23	18
	Specificity %	D ₁	100	57	100	100	71	86
		D ₂	100	61	100	100	83	89
Electronic stable conductance using "universal gold standard"	Sensitivity %	D ₁	61	68	54	54	63	60
		D ₂	48	47	43	48	47	43
	Specificity %	D ₁	100	100	100	100	100	100
		D ₂	83	78	94	83	78	83
Electronic stable conductance using "site specific gold standard"	Sensitivity %	D ₁	65	78	54	68	65	63
		D ₂	46	54	46	46	54	48
	Specificity %	D ₁	91	82	82	100	82	87
		D ₂	83	79	88	83	79	82

Table 5.2 The sensitivity and specificity values obtained for five examiners and five diagnostic techniques for the diagnosis of occlusal caries in 48 premolars only. The mean sensitivity and specificity for each diagnostic technique is also presented.

Examination technique		Diagnostic Threshold	Examiner					Mean
			1	2	3	4	5	
Visual	Sensitivity %	D ₁	45	36	65	66	65	17
		D ₂	66	66	66	66	66	66
	Specificity %	D ₁	93	93	100	100	100	97
		D ₂	100	100	100	100	100	100
FOI	Sensitivity %	D ₁	67	33	65	66	65	21
		D ₂	66	66	66	66	66	66
	Specificity %	D ₁	66	67	100	100	100	93
		D ₂	100	100	100	100	100	100
Radiographic D-quad	Sensitivity %	D ₁	66	66	66	66	65	61
		D ₂	66	66	66	66	13	65
	Specificity %	D ₁	100	100	93	100	100	99
		D ₂	100	100	100	100	100	100
Radiographic B-quad	Sensitivity %	D ₁	66	66	66	66	66	66
		D ₂	66	66	66	66	66	66
	Specificity %	D ₁	100	100	100	100	100	100
		D ₂	100	100	100	100	100	100
Electronic cable conductance using "universal gold standard"	Sensitivity %	D ₁	27	27	24	18	21	23
		D ₂	25	13	66	25	25	18
	Specificity %	D ₁	66	67	73	73	66	76
		D ₂	96	95	93	96	96	93
Electronic cable conductance using "site specific gold standard"	Sensitivity %	D ₁	26	29	26	19	23	25
		D ₂	14	14	66	29	29	17
	Specificity %	D ₁	59	66	77	77	66	76
		D ₂	66	93	93	96	96	93

Analysis of variance of sensitivity values for the whole sample indicated that molars and premolars were different at both the D_1 and D_2 diagnostic threshold of diagnosis ($F = 297$, $P < 0.001$ and $F = 273$, $P < 0.001$ respectively). The variance ratio (F) is estimated by dividing the between groups variance by the within groups variance. Thus, if differences between levels of a factor (groups) are no greater than differences within groups, then the variance ratio will be 1. Separate analyses of the molar and premolar data indicated statistically significant differences between examination techniques and examiners, with larger variance ratios for the former (Table 5.3). To some degree, this indicates that differences between examination techniques were a more profound influence on variation in the data than differences between examiners. Post analysis of variance contrast showed that the sensitivity values obtained with the ECM II were significantly higher at both diagnostic thresholds and for molars and premolars ($P < 0.01$) than the other diagnostic techniques investigated but specificity values were significantly lower ($P < 0.001$) for premolars at the D_1 diagnostic threshold and for molars and premolars at the D_2 diagnostic threshold (Figure 5.5).

5.3.2 Intra-examiner reproducibility.

Intra-examiner agreement was assessed from re-examination of a third of the teeth and the percentage agreement between first and second readings calculated. Table 5.4 shows the percentage agreement achieved by each examiner and the mean for each diagnostic technique. The ECM II readings were also assessed by calculating the limits of agreement, as in Chapter 4, for all the repeated readings of the five examiners on molars and premolars. The mean of the calculated differences between the first and second readings was -0.34 (SD 2.02). Thus the limits of agreement for this pooled data were

+3.7 and -4.4.

Table 5.3 The variance ratios (F) obtained due to the influence of different examiners and different examination techniques on the sensitivity and specificity values at both the D and D₁ diagnostic threshold, and for molars and premolars.

SENSITIVITY

Variable	D ₁ diagnostic threshold		D ₂ diagnostic threshold	
	Molars	Premolars	Molars	Premolars
Examiner	5.33**	3.09*	12.88***	2.41
Examination technique	20.79**	3.90*	86.43***	35.88***

SPECIFICITY

Variable	D ₁ diagnostic threshold		D ₂ diagnostic threshold	
	Molars	Premolars	Molars	Premolars
Examiner	1.68	3.58*	4.63**	1.91
Examination technique	2.89*	12.72***	9.28***	90.79***

*** P < 0.001

** P < 0.01 * P < 0.05

Table 5.4 The percentage agreement achieved by each examiner when molars and premolars were re-examined using each examination technique. The mean value for each diagnostic technique is also presented.

Examination technique	Tooth type	Examiner					Mean
		1	2	3	4	5	
Visual	Molar	75	81	69	81	69	75
	Premolar	88	69	94	100	94	89
POTI	Molar	88	88	88	69	81	85
	Premolar	75	88	94	100	100	91
Radiographs D-speed	Molar	100	63	94	94	69	84
	Premolar	100	100	100	100	88	98
Radiographs E-speed	Molar	94	50	100	100	50	79
	Premolar	100	100	100	100	100	100
Electronic conductance cut-off ≤ 74	Molar	94	81	94	69	94	86
	Premolar	69	81	75	50	81	71
Electronic conductance cut-off ≤ 2.24	Molar	100	100	100	100	100	100
	Premolar	100	100	100	100	100	100
Electronic conductance cut-off ≤ 5.38	Molar	88	81	94	69	94	85
	Premolar	69	81	75	50	81	71

The exact reproducibility of the author in the assessment of the histological validating technique was 88%.

5.3.3 Inter-examiner variation.

Calculation of the coefficients of variation for each diagnostic technique showed, that for molars, there was less variation between the examiners in sensitivity values obtained with the ECM II (7.9%) than with any other diagnostic technique (visual 28-39%; FOTI 27-37%; bitewing radiographs 42-56%). Variation between examiners in specificity values were comparable for the ECM II (0-8%), and visual (2-6%) and FOTI examinations (2-7%), and less than for bitewing radiographs (17-21%). The coefficients of variation calculated for the sensitivity values obtained by the examiners when premolars were examined were bizarre (visual 0-112%; FOTI 0-123%; bitewing 0-173% and 14-64% for the ECM II) perhaps reflecting the difficulty of caries diagnosis in premolars. The coefficients of variation were acceptable and comparable for specificity values obtained with all examination techniques (0-14%).

5.4

Discussion.

In the selection of the teeth for this study, the author aimed to represent a low caries prevalence and to include only small lesions. This follows recommendations put forward by Verdonchot at a satellite symposium of ORCA 1992 (1994) and by Verdonchot *et al.* (1993), who emphasised that inclusion of too many large lesions would lead to an overestimation of sensitivity. For this reason only 6% of the molars and 2% of premolars

were chosen with undermining staining of the dentine shining up through apparently intact enamel, and only 2% of the molars had an actual cavity. Despite this 63% of molars and 17% of premolars showed histological evidence of dentine caries (Figure 5.4). Of the molars with dentine caries, 23% had lesions extending into the pulpal half of dentine. The difficulty experienced by the author in the caries assessment of the teeth in this study is also reflected in the difference between the "site specific gold standard" and the "overall gold standard". The author aimed, in those cases where caries was thought to be present, to identify the worst affected site to take the ECM II readings. However, the deepest aspect of a lesion was distant from this site in 20% of cases.

In a laboratory study, such as this one, it is important to simulate the clinical conditions which might effect visual and FOTI diagnosis. Thus, in this study an impression putty was used to simulate the lips and cheeks of a patient, creating the shadows and restricted access experienced clinically. Despite this, the absence of plaque and the acquired pellicle made visual examination easier. However, sensitivity values were still very poor (Figure 5.5). Visual and FOTI examination resulted in higher sensitivity values at the D_1 diagnostic threshold than at the D_2 level. This was unexpected because logically a greater proportion of deeper dentine lesions should have been correctly identified. However, inclusion of shallower enamel lesions, which logically should have caused greater diagnostic difficulty, actually resulted in an increase in sensitivity. It is likely that the dentists noted stained fissures and white or brown spot lesions as enamel demineralisation but failed to recognise demineralisation in the dentine beneath.

Examination of bitewing radiographs using both D- and E-speed films resulted in lower

sensitivity values at the D_1 diagnostic threshold compared to those obtained by either visual or FOTI examination. This may be due to the fact that few enamel lesions were visible radiographically and demineralisation in dentine must be relatively advanced to be detected on a radiograph because of superimposition of intact buccal and lingual enamel. These low sensitivity values were consistent with those obtained by Russell and Pitts (1991, 1993 a). Premolar teeth presented a major problem (Figure 5.5) as negligible numbers of lesions were detected correctly.

Use of the ECM II by relatively untrained examiners resulted in higher sensitivity values than conventional examination techniques used in general practice. Of interest, the ECM II readings taken at a single site on each tooth gave results representative of the worst affected site on the occlusal surface. That is, no difference was observed between the sensitivity values obtained when ECM II readings were compared with either the "site specific gold standard" or "overall gold standard". However, the ECM II readings were taken at the site most likely to be carious (chosen by the author), thus a process of elimination had taken place. Had the site of the ECM II reading been randomly chosen by each dentist the result may have been different.

The sensitivity values obtained with all the diagnostic techniques were lower for premolars than molars. Occlusal caries diagnosis in premolar teeth is not regarded in the literature as a major issue when compared to that in molar teeth. As such, the dentists in this study may have given only cursory attention to these teeth. The lower prevalence of caries in the premolar sample may also have a bearing on the sensitivity values; this has been sited as a factor possibly affecting these values (Verdonschot *et al.*, 1993).

The specificity values obtained with all the diagnostic techniques were acceptable, however, the ECM II did lead to lower values when compared to visual and FOTI examinations. This reduction in specificity was small when compared to the benefit gained in sensitivity. The lower specificity values may be partly explained by the fact that the "site specific gold standard" and the "overall gold standard" differed. In 6 teeth the site at which the ECM II readings were taken was sound, but adjacent areas were carious and similarly, in 4 teeth the ECM II readings were taken over enamel lesions but at an adjacent site the caries extended into dentine. It is possible that subsurface communication with a deeper part of a lesion could result in an increased conduction of the electric current than would be expected. This phenomenon has been suggested previously by Rock and Kidd (1988) and may explain the difference in specificity between the two ECM II readings in Figure 5.5 A when compared to the two gold standards. It is also possible that increased conduction may result from a fissure which extends through the entire thickness of the enamel to expose the dentine.

Analysis of variance confirmed that the sensitivity and specificity values differ between examiners, but suggested the greater influence on these values was the examination technique. Calculation of the percentage agreement for each examiner showed intra-examiner reproducibility to be good irrespective of the diagnostic technique. The lowest mean value calculated for intra-examiner reproducibility was for the ECM II when used on premolars (Table 5.4). However, these led to a percentage agreement of 71% which is acceptable when weighted against the sensitivity values and encouraging considering the technique was new to the dentists and they were given relatively little training in it. The limits of agreement for the pooled data collected for all repeated readings from all

the examiners in this study (+3.7 and -4.4) was almost identical to those achieved by the author in Chapter 4 (+3.3 and -4.4). This is interesting because the author is very familiar with the electronic diagnosis technique whereas the 5 dentists were very inexperienced. It is possible that the technique is easy to learn. This means that 95% of ECM II stable conductance readings when repeated are likely to vary by up to +3.7 and -4.4. Although this range in error appears large, it is important to appreciate that these figures reflect extreme errors and that most repeated readings will differ by smaller amounts. This means that changes in conductance readings, obtained by the same dentist, when repeated at a recall appointment are likely to predict reliably changes in lesion severity rather than reading error. Indeed if the dentine level of caries involvement were to initiate operative treatment and the cut-off stable conductance value of 2.24 (for the D₃ diagnostic threshold) used to assess intra-examiner agreement, the technique was perfect (Table 5.4) and reliable.

Inter-examiner variation was assessed by calculating the coefficients of variation for each examination technique. The results imply that less variation in sensitivity values will result between examiners when the ECM II is used, than would be obtained with visual or radiographic examination. This finding may be because the ECM II readings were objective and free from the subjective interpretation of each examiner. Whilst the statistical significance of the lower variation obtained with the ECM II has not been tested, the potential use of the electronic diagnostic technique by epidemiologists in a National Survey is evident and the question of inter-examiner reproducibility needs further investigation.

5.5**Conclusions.**

The conclusions that can be drawn from this study are:

- 1. Electronic diagnosis of occlusal caries resulted in an increase in sensitivity and decrease in specificity compared to visual, FOTI and radiographic examination techniques when used by dentists who were relatively unfamiliar with the FOTI and electronic techniques.**
- 2. Examiners differed within themselves when asked to re-examine teeth but, weighted against the sensitivity values obtained, the ECM II produced good results. Intra-examiner reproducibility was, however, acceptable for all examination techniques and the ECM II produced results comparable to those for visual, FOTI and radiographic examinations.**
- 3. Inter-examiner variation was found to be less for ECM II readings than for visual, FOTI and radiographic examinations.**

CHAPTER 6:

OPERATIVE AND MICROBIOLOGICAL VALIDATION OF VISUAL, RADIOGRAPHIC AND ELECTRONIC DIAGNOSIS OF OCCLUSAL CARIES IN NON-CAVITATED TEETH JUDGED TO BE IN NEED OF OPERATIVE CARE.

6.1

Introduction.

The diagnostic methods included in the preceding chapter are based upon the identification of demineralised tooth tissue. The demineralisation is caused by the acids produced by oral bacteria and it precedes cavitation and bacterial ingress (Sognnaes and Wislocki, 1950; Fusayama *et al.*, 1966). Clinically visible cavitation occurs at a late stage in occlusal caries. Current diagnostic techniques are not able to differentiate uninfected from infected demineralised tooth tissue in the non-cavitated occlusal surface. Some would suggest that clinical cavitation unequivocally calls for restoration (van Amerongen *et al.*, 1992). Others claim that dentine lesions with clinically intact or cavitated occlusal surfaces can be fissure sealed and will not progress due to a reduction in the number of viable organisms (Mertz Fairhurst *et al.*, 1986; Handelman *et al.*, 1986; Jensen and Handelman, 1980). In this situation the fissure sealant is used therapeutically, and not preventively. This approach assumes that the nutritional source for the bacteria is virtually eliminated by placement of a sealant and that nutritional support from the vital pulp is insufficient to maintain the viability of the microflora. However, others (Weerheijm *et al.*, 1992 c) suggest that dentine caries beneath sealants may not revert to a completely inactive state and that the number of microorganisms in the underlying dentine is not related to the apparent integrity of the fissure sealant. Therefore, once the carious process has reached

the point where bacteria have infected the dentine, removal of the infected tissue and its replacement with a filling may be the treatment of choice (Fusayama, 1979).

Many studies, including the present work, have attempted to correlate the degree of demineralisation of dentine beneath apparently intact occlusal enamel with visual, radiographic and electronic caries diagnosis using a histological gold standard. However, it may also be relevant to know whether such tissue is infected since the latter would indicate that restorative treatment is required.

The present clinical study had the following aims:

1. To validate clinically dentists' decisions to restore occlusal caries by investigating the dentine at operation to see whether it was:
 - a demineralised or
 - b infected.
2. To investigate which diagnostic techniques (visual, radiographic or electronic) best predicted the presence of infected dentine in need of operative treatment.
- 3 To correlate clinical findings during cavity preparation with the degree of bacterial infection of the dentine.

6.2

Materials and Method.

6.2.1 Tooth selection.

Forty five patients, aged 14-55 years, were referred to a single operator (the author) for occlusal restorations. The referrals were made by a number of clinical teachers in the Department of Conservative Dentistry (Guy's Hospital Dental School, UMDS) who, using conventional visual and radiographic examinations, decided that one or more teeth required operative treatment. No attempt was made to identify which visual and/or radiographic criteria were used.

6.2.2 Preoperative assessment.

Bitewing radiographs were available for all patients and the radiographic appearance of the occlusal aspect of the tooth was recorded as sound, or as having caries in the outer, middle or pulpal third of dentine.

The operator examined each tooth visually and decided which area of the fissure was most likely to be carious. This site was then examined with the Vanguard Caries Detector. For consistency, the Vanguard Caries Detector was used for all the readings, because this study commenced before the ECM II was constructed.

The investigation site was cleaned with a sharp sterile needle to remove surface plaque thus minimising subsequent contamination of the underlying dentine. The appearance of the clean and dry investigation site was recorded as either sound, stained, or having a white or brown spot lesion or undermining stain. Undermining stain describes the grey

appearance around a fissure where caries in dentine is apparently shining through intact enamel (Kidd and Joyston Bechal, 1987). Where a site showed undermining stain in addition to superficial fissure staining or white or brown spot lesions in enamel, the appearance was recorded as undermining stain only.

6.2.3 Clinical technique.

Anaesthesia was obtained and the tooth isolated with rubber dam. A sterile tungsten carbide bur (Jet 330, Kerr UK, Bretton, Peterburgh, UK) was used in the air rotor to remove enamel at the sample site until the enamel dentine junction was reached. At this stage the dentine at the sample site was washed, dried and examined (Kidd *et al.*, 1993 a). Using a sterile probe tip (Ash No. 6, Claudius Ash, Potters Bar, Herts, UK), the consistency of the dentine was assessed as soft (probe readily enters tissue), medium (probe enters tissue if pressed firmly) or hard (as hard as surrounding tissue). The colour of the dentine was matched to a small, specially designed shade guide and rated as dark-brown, mid-brown or pale. Finally, the sample site was entered with a sharp probe and if the tissue oozed moisture it was graded as wet and if it did not, it was assessed as dry.

A standardised sampling procedure was then used to obtain a dentine sample at each site. For this a sterile number 3 (012) round bur (Claudius Ash, Potters Bar, Herts, UK) was dipped into fastidious anaerobic broth (FAB, Lab M Ltd., Bury, Lancs, UK) contained in a screw top vial (2ml cryotube, Nunc, Renfrewshire, Scotland) and was used in a slow handpiece to remove a burfull of tissue. The bur was placed into 1ml of FAB, shaken to dislodge the adherent dentine and removed with sterile tweezers before being placed on ice. At this stage a caries detector dye (1% acid red in propylene glycol, UMDS

Pharmacy) was applied for 10 seconds (Fusayama, 1979). The tooth was then rinsed and dried and the enamel and dentine at the sample site assessed as being dye-stained or dye-stain free. Subsequently, cavity preparation was completed and the tooth restored using conventional techniques.

6.2.4 Microbiological Processing

This was carried out by Dr. David Beighton, Reader in Oral Microbiology (Oral Microbiology, Royal College of Surgeons, Department of Dental Sciences, King's College School of Medicine and Dentistry, Denmark Hill, London SE1 9RW). Dentine samples were vortexed for 15 seconds with sterile glass beads (3.5-4.5 mm in diameter, BDH, Poole, Dorset, UK), decimally diluted in FAB, and 100 μ l volumes of appropriate dilutions were plated onto a range of bacteriological media. These were Mitis Salivarius Agar (MSB, Difco Laboratories, Teddington, Middlesex, UK) supplemented with sucrose and bacitracin at final concentrations of 20% (w/v) and 0.2 units/ml, respectively (Gold *et al.*, 1973), for the isolation of mutans streptococci, Rogosa agar (Oxoid, Basingstoke, Hants, UK) for the isolation of lactobacilli, Sabouraud dextrose agar (Oxoid) for the isolation of yeasts and fastidious anaerobe agar (FAA) supplemented with 5% (v/v) horse blood. FAA was used to obtain a total anaerobic colony count. These media were incubated anaerobically at 37°C; MSB and Rogosa agar for 3 days and FAA for 7 days, while Sabouraud dextrose agar was incubated aerobically for 2 days.

Mutans streptococci were counted on MSB and, due to their characteristic colony morphology, on the FAA plates. The maximum colony count was used in the analyses.

Mutans streptococci (*S. mutans* and *S. sobrinus*) were identified using a simple

biochemical identification scheme (Beighton *et al.*, 1991 a). Lactobacilli and yeasts were identified as described previously (Beighton *et al.*, 1991 b).

6.2.5 Statistical analysis.

The individual bacterial counts (mutans streptococci and lactobacilli) were expressed as a percentage of the total colony count on FAA. If the colony count on any media was zero, this value was used in the subsequent analyses. Mean and standard errors of bacterial counts expressed at $\log_{10}(\text{CFU per sample} + 1)$, and bacterial percentages were calculated. Means were compared using the appropriate t-test for dichotomous data and for paired samples, while one-way analysis of variance was used for data with greater than two categories with means compared using Duncan's multiple range test.

6.3

Results.

A total of 82 teeth were investigated; 3 premolars and 79 molars.

6.3.1 Preoperative assessment.

Radiographs showed 32 teeth (39%) as sound and 50 teeth (61%) with obvious occlusal dentine caries. Of these 39 had a radiolucency confined to the outer third of dentine and 11 a radiolucency involving the middle third of dentine. There were no teeth with a radiolucency in the pulpal third of dentine.

The Vanguard gave a reading of 9 (caries in dentine) in 63 sites (78%) and a reading of 0 (sound site) in 5 sites (6%). The remaining 13 sites (16%) gave readings between 3 and

8.

On visual diagnosis only 4 sites (5%) were sound, 38 (46%) were stained, 15 (18%) had white or brown spot lesions and 25 (31%) had undermining stain as the predominant feature.

6.3.2 Assessment of demineralisation during cavity preparation.

Clinical examination of dentine once the overlying enamel had been removed showed 32 sites (39%) were soft, 28 sites (34%) were medium and 22 sites (27%) were hard. When the sites were assessed as wet or dry, 20 sites (24%) were classed as wet and 62 (76%) dry. The dentine was pale at 10 sites (12%), mid brown at 29 sites (35%) and dark brown at 43 sites (52%).

Use of the caries detector dye to confirm dentine demineralisation showed that in 79 sites (96%) the dentine stained red. In the remaining 3 sites (4%) there was no staining of the dentine with the dye but clinical examination revealed a white spot lesion in the enamel indicative of enamel demineralisation.

6.3.3 Microbiological examination.

6.3.3.1 Correlation with radiographic diagnosis.

Figure 6.1 shows the mean total colony forming units, mutans streptococci and lactobacillus counts for the sites classified according to radiographic appearance. A significant difference ($p < 0.05$) between the three radiographic categories (sound, caries

in outer third and middle third of dentine) was found for the total colony forming units and the lactobacillus counts. Although there was a significant increase in mutans streptococci when caries was visible radiographically ($p=0.05$), no significant difference was observed with increased radiographic depth.

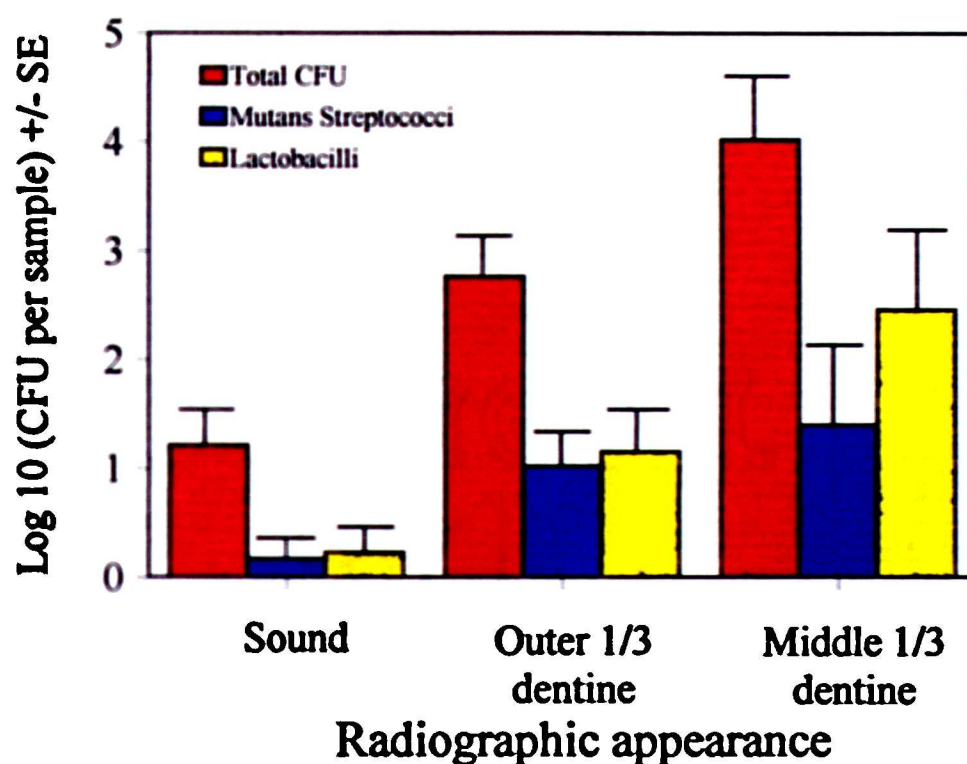


Figure 6.1

The association between the radiographic appearance and the total number of bacteria (total CFU), lactobacilli and mutans streptococci (M-S) recovered from standardised dentine samples.

6.3.3.2 Correlation with electronic diagnosis.

Figure 6.2 shows a scattergram relating the total colony forming units to the Vanguard reading. The majority of readings were 9, and there was no significant correlation between the Vanguard reading and the level of infection in the dentine ($r=0.04$, $p>0.5$).

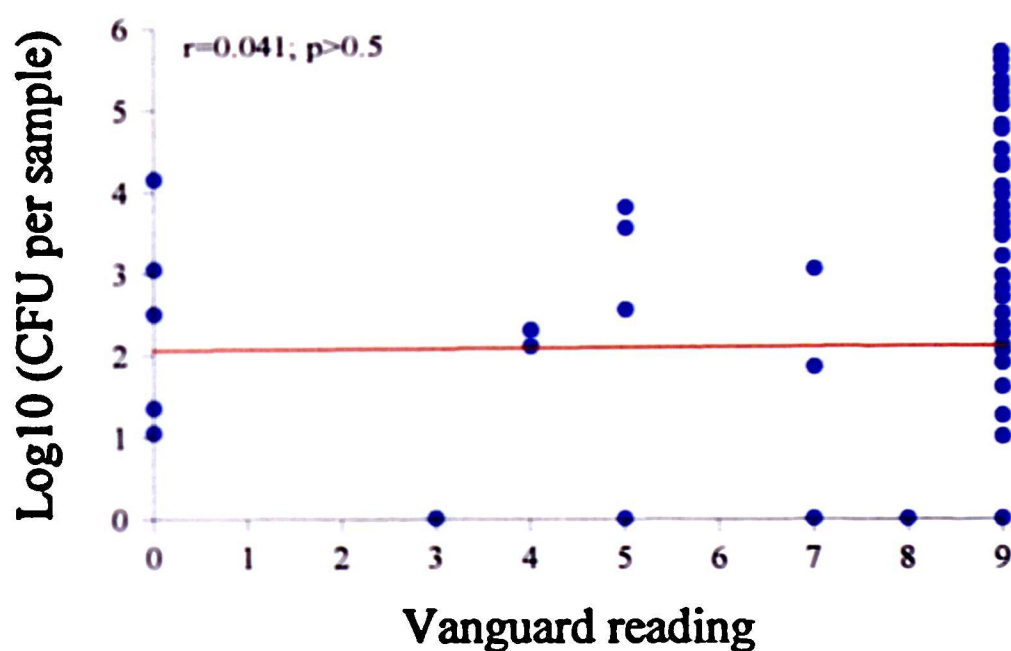


Figure 6.2 A scattergram showing the relationship between \log_{10} (total CFU) and Vanguard reading for all 82 sites. The line represents the linear regression.

6.3.3.3 Correlation with visual diagnosis.

Figure 6.3 shows a scattergram relating the total colony forming units to the various visual criteria. Very few sites were clinically sound or had a white spot lesion. There was no significant correlation between the visual appearance of the site and the level of infection in the dentine ($r=-0.009$, $p>0.5$).

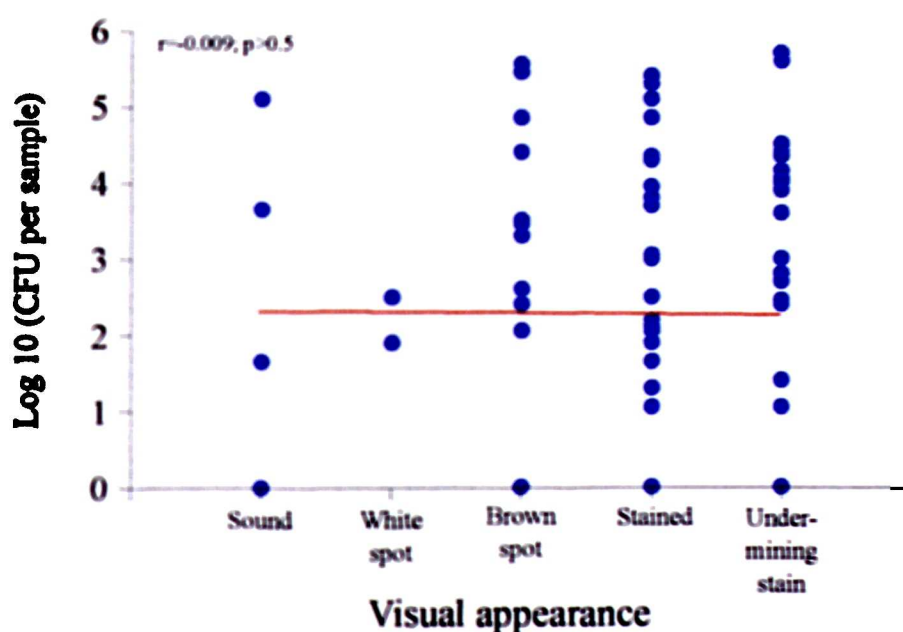


Figure 6.3 A scattergram showing the relationship between \log_{10} (total CFU) and the visual appearance for all 82 sites. The line represents the linear regression.

6.3.3.4 Correlation with clinical criteria recorded at operation.

The texture of the dentine, soft, medium or hard, was significantly related to bacterial counts. Soft dentine harboured significantly more bacteria, mutans streptococci and lactobacilli ($p < 0.05$) (Figure 6.4). Similarly wet dentine yielded significantly more bacteria ($p < 0.001$), mutans streptococci ($p < 0.01$) and lactobacilli ($p < 0.001$) than dry dentine (Figure 6.4). Dentine colour (dark brown, mid-brown or pale) was not significantly related to bacterial counts (Figure 6.4).

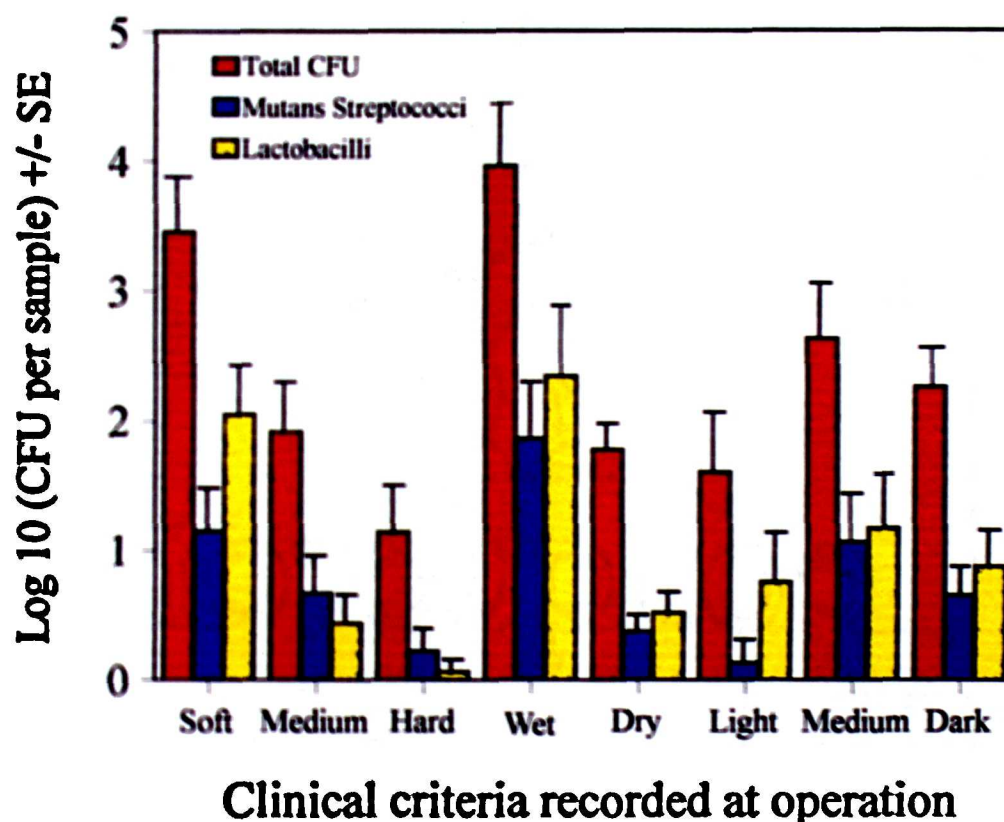


Figure 6.4 The association between lesion consistency (soft, medium or hard), moisture content (wet or dry) and colour (pale, mid-brown or dark brown), and total number of bacteria (total CFU), lactobacilli and mutans streptococci recovered from standardised dentine samples.

6.4

Discussion.

It is important to appreciate that in this clinical study, the occlusal surfaces had been diagnosed previously as carious and in need of operative intervention by various dentists, prior to the assessments made by the operator (the author). The operator was unaware of the criteria which prompted the clinician's decision, but they did not have access to the Vanguard. It must be presumed, therefore, that they used a combination of visual assessment and appearance on bitewing radiograph together with patient factors such as age, caries restoration status and oral hygiene.

Use of the caries detector dye showed that using these criteria the dentists never selected sound teeth and rarely selected demineralised lesions confined only to enamel for operative treatment. It is claimed that this dye stains the irreversibly altered organic matrix of demineralised dentine (Fusayama, 1979). Some studies have shown the dye stain to correspond reasonably well to bacterial penetration but the acid red staining and bacterial penetration are separate phenomena and cannot be expected to correspond exactly (Boston and Graver, 1989). In the present study the dye was applied after the sampling of the dentine. This was done in case the dye affected the bacterial counts although previous studies have indicated that the dye is non toxic to the bacteria (Kidd *et al.*, 1993)

b) Despite the fact that the dye was used after a burfull of tissue had been removed, the dentine in all but three cavities still took up the dye stain, indicating demineralisation. However, in the three cases where the remaining dentine did not stain, it is possible that all the dye stainable dentine may have already been removed by the sampling procedure.

The electronic caries detector confirmed dentine demineralisation in 78% of teeth, but the referring dentists did not have access to this instrument nor did they apparently need it to select such teeth. Since it is not ethical to operate on a control group considered clinically sound, it is not possible to see how many false negative diagnoses (surface diagnosed as sound but found to be carious on cavity preparation) these clinicians generate. It can only be stated that if dentine demineralisation should trigger operative intervention, there were very few false positive diagnoses.

However, were all these sites in need of operative intervention? It is known that in the carious process demineralisation precedes bacterial infection (Sognnaes and Wislocki, 1950; Fusayama *et al.*, 1966). It would seem logical to suggest that demineralisation with minimal bacterial infection could be managed by conservative techniques such as fissure sealing, but heavy infection may represent a point of no return when operative intervention is indicated (Weerbeijm *et al.*, 1990). For this reason microbiological sampling was used in this study to assess the level of infection of the demineralised dentine. Samples for microbiological analysis were obtained on sterile round burs. It was not possible to weigh the bur before and after sample collection to determine the weight of dentine removed because the bur was so much heavier than the dentine sample. Thus a "burfull of tissue" represents a standardised sample. The results were therefore expressed per sample rather than by weight of tissue removed. There is a potential source of error here. However, sound dentine should be sterile and the numbers of bacteria differed between samples by as much as 10,000 fold. It is not conceivable that such differences could be achieved by differences in the weight of tissue removed.

The minimum numbers of bacteria in the standardised sample that indicates an active demineralisation process is difficult to determine from these data. The possibility of contamination of samples must be considered. Rubber dam minimises salivary contamination but in gaining access to dentine, plaque may be carried from the fissure into the cavity. Despite these problems, previous work has confirmed the reproducibility of the sampling procedure by showing that duplicate samples of dentine, taken from individual sites with the same clinical appearance (consistency, texture, colour) within the same cavity, showed similar levels of bacterial growth (Kidd *et al.*, 1993 a).

Using microbiological validation the radiograph was the best predictor of bacterial infection. Bacterial counts obtained from radiographically sound fissures were very low. However, when the lesions were radiographically visible a significant increase in the level of dentine infection was found.

If it is accepted that the teeth requiring operative intervention are those where the dentine is heavily infected, neither visual diagnosis nor the electronic caries detector were helpful in deciding when to place a filling. Visual diagnosis was unrelated to the level of infection of the dentine. Similarly, although the Vanguard will detect dentine demineralisation at a much earlier stage than any other diagnostic technique investigated, it will not predict the presence of bacteria in dentine. It would seem that teeth which are sound on radiograph, but register as carious electronically, harbour so few bacteria that preventive techniques such as fissure sealing might be the appropriate management. The role of the Vanguard and the new ECM II therefore, may be to screen for early demineralisation in the absence of bacterial infection of the dentine, so that preventive techniques may be

targeted at an appropriate population. The Vanguard and ECM II therefore, may be used to monitor lesion initiation, arrest, remineralisation or progression (increasing enamel porosity) at a subsequent visit.

The final validation used in this study was the operative assessment of the dentine during cavity preparation. Although subjective, these clinical criteria were highly consistent at predicting the level of infection in the dentine. Standardised samples from dentine that were soft and wet when probed, cultured significantly more total bacteria, mutans streptococci and lactobacilli than medium, hard or dry dentine. The colour of the dentine was not related to the number of bacteria in the samples. These results were consistent with those found in a previous study of 205 primary and secondary carious lesions assessed during cavity preparation (Kidd *et al.*, 1993 a).

The practitioner does not therefore need expensive microbiological tests to audit his/her clinical diagnosis. Having decided to restore, the consistency of the dentine at operation can be used to check the original diagnostic decision. If soft, wet dentine is found at operation then heavily infected tissue is present. If, on the other hand, the dentine is dry and hard it is minimally infected and a preventive technique might have been more appropriate management. Each cavity then becomes its own little clinical trial with the operator continually checking and refining his/her diagnosis and treatment regimens.

Non-cavitated occlusal fissures, diagnosed as carious and requiring restoration, exhibited a range of visual appearances of which no particular feature was indicative of its condition. Similarly visual appearance was not predictive of bacterial infection of the

dentine. Demineralised tissue was detected reliably using the Vanguard, but it too was unable to predict bacterial infection of dentine. Although the radiograph failed to reveal 39% of the demineralised lesions in this study, it was a good predictor of bacterial infection in dentine. Those lesions missed radiographically were minimally infected and safe to treat preventively, while radiographic evidence of demineralisation was associated with heavy bacterial infection of dentine and indicated the need for operative treatment.

6.5

Conclusions.

The conclusions that can be drawn from this study are:

- 1 The referring dentists never selected sound teeth and rarely selected demineralised lesions confined only to enamel for operative treatment. However, not all of these lesions were heavily infected.
- 2 Radiolucency in dentine on bitewing radiograph was the best predictor of infected dentine. Neither visual nor electronic diagnosis correlated well with infection of dentine.
- 3 During cavity preparation the clinical findings that predicted heavily infected dentine were texture (soft) and moisture content (wet).

CHAPTER 7

OVERALL RESISTANCE READINGS USING A CONTACT MEDIUM AND NO AIRFLOW.

7.1 Introduction.

The literature review drew attention to the difficulties faced by clinicians and epidemiologists when diagnosing occlusal caries. In a National Survey, the epidemiologist is interested in the carious status of each tooth surface at the D₂ (dentine caries) level of diagnosis. More accurate information about individual sites within a single surface may be of interest to a clinician, but are superfluous to the epidemiologist. It is known that the occlusal surface may have a pit and fissure pattern concealing multiple discrete lesions of varying severity (König, 1963; Mortimer, 1964), therefore, a single reading reflecting the site on the occlusal surface with the worst carious lesion (if present) would seem more appropriate for the epidemiologist.

Chapters 2 to 6 investigated electronic readings taken with the Vanguard and the ECM II, which both had airflow around the probe tips to give site specific readings. In Chapter 2, the Caries Meter L was investigated for use without an airflow for site specific caries diagnosis. In this technique the teeth had to be dried before a reading was taken and a drop of saline was used to provide a good electrical contact between the probe tip and the tooth. A criticism of this technique was that uncontrolled flow of the saline along the fissures increased the surface area of contact which might result in electrical contact with an adjacent part of the fissure with a deeper lesion. This could explain the lower

specificity for site specific readings obtained with the Caries Meter L in comparison to the Vanguard. It is possible that use of a more viscous contact medium with little flow, such as a gel, could overcome this problem. The epidemiologist, on the other hand, might be best served by deliberately spreading the contact medium along the fissure to obtain an overall resistance reading so that the current that would flow would reflect the worst affected site. However, the increased area of contact with the tooth would lead to lower resistance values generally and this would necessitate the establishment of new diagnostic cut-off values for caries diagnosis.

The present study had the following aims:

1. To determine the accuracy and reproducibility of site specific readings taken with an electrical contact gel and no airflow.
2. To determine the accuracy and reproducibility of overall resistance readings obtained by completely covering the pit and fissure pattern with the contact gel.

7.2

Materials and method.

The teeth used in this study were those selected and used in Chapter 5. These teeth were only used after all the dentists involved in that study had completed their examinations. For this study, the teeth were removed from the saline storage medium and one to four sites, including the one which appeared to be the most likely to be carious, were chosen and recorded on the plan of the pit and fissure system. The teeth were replaced in the saline before and between experimental readings.

The readings in this study were taken with the ECM II (operated at the same frequency, alternating current as previously, that is 21 Hz), however, the machine was operated at an alternative setting. A switch on the display panel of the machine converted the digital stable conductance reading to that of a stable resistance measurement on a scale 0 - 2 M Ω . As before an audible bleep sounded at the commencement of the reading and again when the resistance value had remained the same for three consecutive seconds. The technique for taking the resistance measurement was similar to that described for the Caries Meter L. The teeth were removed from the saline and held in the same hand as the hand-held connector. A three-in-one syringe was used to dry the tooth and at each investigation site a drop of KY jelly (Johnson & Johnson Ltd., Maidenhead, UK.), impregnated with a red dye, was placed which acted as a contact medium. The probe tip of the ECM II was then placed in the jelly and a reading taken without any airflow. This reading was therefore equivalent to the site specific readings taken in the previous experimental chapters. A total of 207 site specific readings were taken. Between each reading the teeth were rinsed thoroughly with the three-in-one syringe, to remove the KY jelly, and placed back into the saline to rehydrate.

A second technique was used to take an overall reading of the entire fissure pattern. This technique was carried out as for the site specific readings just described, with the exception that the coloured KY jelly was spread along the entire fissure pattern, ensuring that it was continuous. The probe tip of the ECM II was then placed randomly anywhere in the jelly and the reading taken (total 96). Both the site specific and overall stable resistance readings were repeated on a third of the teeth (those used for the equivalent analysis in Chapter 5) after a period of at least a week had elapsed (a total of 68 site

specific and 32 overall readings).

7.2.1 Histological validation.

The teeth were then sectioned and analysed as described in Chapter 5, ensuring that the sections cut included the area beneath the investigation sites used for the site specific readings. These single sections were used for the "site specific gold standard", whereas to obtain the "overall gold standard" all sections from each tooth were examined to find the deepest recorded lesion.

7.2.2 Statistical analysis.

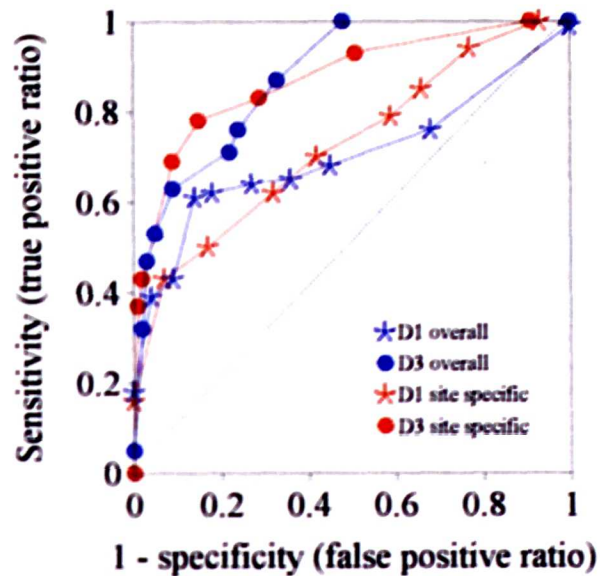
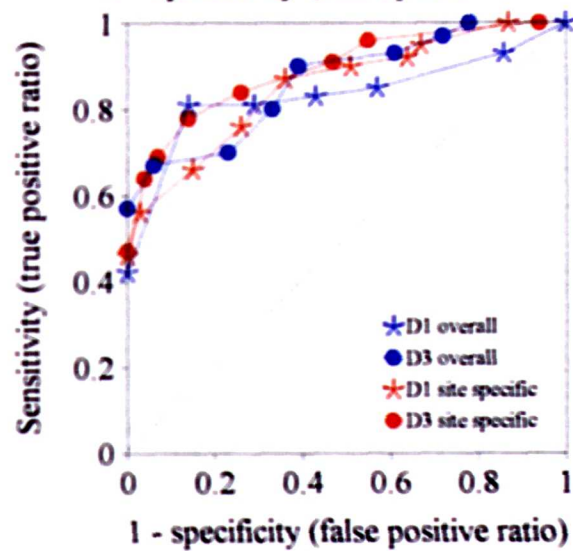
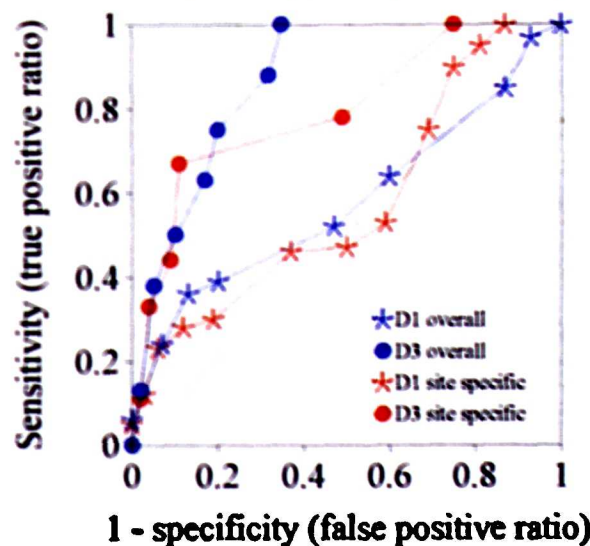
The sensitivity and specificity of the site specific and overall ECM II stable resistance readings were calculated for the D_1 and D_2 diagnostic threshold using various resistance cut-off points. ROC curves were then drawn as described by Campbell and Machin in 1990 and in Chapters 1 (pages 36-38) and 4 (page 124). This was done for the whole sample and for molars and premolars separately. Using the cut-off points that gave the optimum sensitivity and specificity for the whole sample, the results were divided into dichotomous data and the level of reproducibility assessed for both site specific readings and overall readings, using kappa statistics. The limits of agreement were also calculated for each reading type as described by Bland and Altman (1986) and in Chapters 1 (page 41) and 4 (page 126).

7.3

Results.

Site specific stable resistance readings were taken of 207 sites, 118 (57%) in molars and 89 (43%) in premolars. Histological examination of molar sites revealed that 33% (39) were sound, 14% (16) had enamel caries confined to the outer half and 15% (18) extending to the pulpal half of the enamel, 33% (39) had dentine caries confined to the outer half and 5% (6) extending to the pulpal half of dentine. Similarly, for premolar teeth, 36% (32) were sound, 27% (24) had enamel caries confined to the outer half and 27% (24) extending to the pulpal half of the enamel, 10% (9) had dentine caries confined to the outer half and none extending to the pulpal half of dentine. The percentage frequency distribution of the overall gold standards can be seen in Figure 5.4 (page 164).

The ROC curves obtained for the site specific and overall stable resistance readings at both the D_1 and D_2 diagnostic thresholds can be seen in Figure 7.1 A for the whole sample and Figure 7.1 B and C for molars and premolars respectively. The optimum sensitivity and specificity values were taken as that point closest to the top left-hand corner of the axis. The optimum sensitivity values obtained for the overall and site specific readings taken of the whole sample at the D_1 diagnostic threshold were similar, namely 61% (cut-off above and including which indicated a sound reading = 0.448 MΩ) and 62% (cut-off 0.607 MΩ) respectively. However, the corresponding specificity value for the site specific readings (68%) was much lower than that obtained for the overall reading (86%).

A**B****C****Figure 7.1 A-C**

ROC curves obtained for site specific and overall stable resistance readings taken with no airflow and a contact gel at both the D_1 and D_3 diagnostic thresholds. A shows ROC curves for the whole sample, B for molars only and C premolars only.

At the D_2 diagnostic threshold the optimum sensitivity values were again similar for the whole sample (overall reading 76%, cut-off = 0.419 M Ω ; site specific = 78%, cut-off 0.407 M Ω), but higher than that obtained at the D_1 level. However, at this diagnostic threshold the specificity was lower for the overall readings (76%) than that for the site specific readings (85%).

Reproducibility was assessed on 32 teeth (a third of the sample), thus there were 32 overall stable resistance readings and 68 site specific readings repeated. Using the stable resistance cut-off values that gave the optimum sensitivity and specificity values for the whole sample, the results for each technique were split into dichotomous data. At the D_1 diagnostic threshold, the kappa values were 0.76 for the overall readings and 0.51 for the site specific readings. This result was almost reversed at the D_2 diagnostic threshold, with kappa values of 0.55 for the overall readings and 0.71 for the site specific reading. However, calculation of the limits of agreement indicated that an overall resistance reading may vary by up to +0.263 M Ω and -0.217 M Ω and site specific readings by +0.559 M Ω and -0.593 M Ω (Figure 7.2).

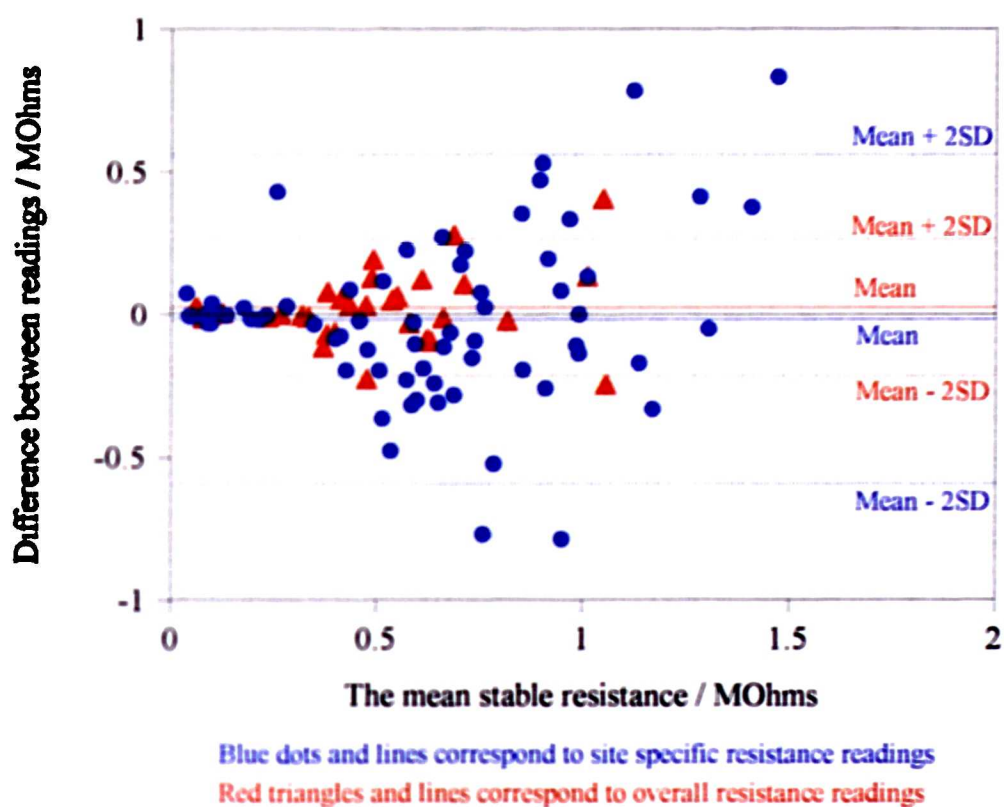


Figure 7.2 Graphic illustration of the difference and mean value calculated between repeated pairs of site specific and overall resistance readings. The horizontal lines represent the mean difference and calculated upper and lower limits of agreement for each type of reading.

7.4

Discussion.

This *in vitro* study may be regarded as a pilot for a completely new approach to electronic diagnosis of occlusal caries. KY jelly was used in this study as a contact medium because it was water soluble, viscous, easily obtained and all of the components have been tested and accepted for intraoral use. Addition of a dye was essential to observe any flow and assess tooth coverage. The contact area provided with the KY jelly was difficult to control and contributed to the variation when the readings were repeated. The variation in this area accounted for a larger proportion of the surface area of contact for site specific readings compared to the overall reading, with the result that reproducibility was inferior. Any ionic contact media suitable for intraoral use could replace the KY jelly, for example toothpaste. However, the conductivity of the substance is important and could affect the results obtained and different resistance cut-off points for diagnosis may be required. The resistance values obtained changed little with time compared to the readings taken with an airflow, thus the readings achieved the stable 3 second period almost immediately.

In this study, both site specific and overall resistance readings produced good and comparable optimum sensitivity values at the D_1 and D_2 diagnostic thresholds. However, the optimum specificity value for the site specific readings at the D_1 diagnostic threshold was unacceptably low (68%). This reinforces the earlier impression that uncontrolled flow of the contact medium to an adjacent region of the fissure with a deeper lesion, may lead to resistance values lower than expected from the appearance of the histological section beneath individual investigation sites.

The reproducibility of site specific readings was also poor, the limits of agreement meant that readings could be expected to vary by $+0.559\text{ M}\Omega$ and $-0.593\text{ M}\Omega$ when repeated. Because no airflow was used in this study and KY jelly was used as a contact medium, the area of effective electrical contact was variable and larger than that obtained for site specific readings taken with airflow. This resulted in lower and more variable resistance values (Hoppenbrouwers *et al.*, 1986). The possible error involved in taking site specific readings with this method reflected approximately 25% of this lower resistance scale of 0 - 2 M Ω . This error also resulted in a low kappa value (0.51) when the results were split into dichotomous data about the cut-off point for the D_1 diagnostic threshold. These disadvantages restrict the use of site specific readings to the diagnosis of dentine caries, for which sensitivity, specificity and reproducibility were good (78%, 85% and kappa 0.71).

The results discussed above were for the whole sample; Figure 7.1 B and C show the relevance of tooth type. In Figure 7.1 B, the results obtained for molars show there is little difference in the position of the ROC curves for both examination techniques and diagnostic thresholds. The curves occupy the top left hand corner of the graph, which reflects a high degree of accuracy. However, Figure 7.1 C for premolars shows that at the D_1 diagnostic threshold the ROC curves are close to the diagonal line $x=y$. This indicates that both techniques produced a false positive result at the same rate as true positive results. Diagnosis of dentine caries only (D_2 diagnostic threshold) in premolars did, however, produce better results. If a specificity above 80% was regarded as acceptable, the sensitivity for the overall readings was 75% and site specific readings 67%. These results approach the corresponding ones obtained in molars.

The accuracy and reproducibility of the overall resistance readings make this technique an exciting possibility for use by epidemiologists in both National Surveys and clinical trials. Each type of study requires a different level of diagnostic accuracy. In a National Survey for example, diagnosis at the D₁ level (that is dentine caries) is important. To date, in such surveys the teeth have been visually examined when wet and plaque covered. The results from Chapter 5 have demonstrated that even under ideal laboratory conditions diagnosis of dentine caries from a visual examination is poor. Whilst use of bitewing radiographs may detect large lesions missed visually, it too results in poor sensitivity values. In a National Survey the epidemiologist is also restricted by ethical considerations on radiography for data collection alone. The overall resistance readings have the potential to represent the prevalence of dentine caries more accurately than any other technique available; teeth do not need to be cleaned prior to examination as the plaque filled fissure pattern will facilitate conduction to the site of deepest caries. Such readings also have great potential in clinical trials of therapeutic agents (eg. toothpaste).

7.5 Conclusions.

The conclusions that can be drawn from this study are:

1. Site specific readings taken with an electrical contact medium and no airflow produced clinically acceptable results except at the D₁ diagnostic threshold in premolars, but were not reproducible due to uncontrolled flow of the medium.
2. Overall resistance readings produced results as accurate as the site specific readings, however, the reproducibility of readings was improved to an acceptable level. This technique therefore provides the epidemiologist with a plausible and exciting technique to aid occlusal caries diagnosis.

CHAPTER 8:

GENERAL DISCUSSION.

8.1 Electronic diagnosis and fissure morphology.

This thesis began by reviewing the literature about pit and fissure development and morphology together with the histology of carious lesions. This helped to explain the difficulties of both visual and radiographic diagnosis. Visual interpretation of non-cavitated fissures in this thesis has shown that specific features do not predict reliably enamel or dentine caries (Chapter 2, 5 and 6). In line with other work this thesis has shown visual diagnosis to result in low sensitivity values (Kay *et al.*, 1988; Lussi, 1991; Wenzel *et al.*, 1991 b; Ketley and Holt, 1993; Lussi, 1993; Ricketts *et al.*, 1995). However, previous studies (Lussi, 1993; Ricketts *et al.*, 1995) have shown an improvement in sensitivity values for dentine caries diagnosis when bitewing radiographs were examined, the radiographs used in this thesis did not improve the diagnosis. The difference may be explained by differences in lesion depth; throughout this thesis, an attempt has been made to include only shallow dentine lesions, whereas lesions in the previously mentioned studies would appear to have been deeper.

Whilst tooth and specifically fissure morphology hinders visual and radiographic diagnosis, it facilitates electronic diagnosis. The invaginated fissure, with its contents, ensures good electrical contact between the probe tip and the lesion. Since the enamel lesions frequently occur in the depths of the fissure, the surface area of the lesion is not exposed on the occlusal surface, thus when an airflow is used very rapid dehydration does not occur. However, a smooth surface lesion with a large exposed surface area, has the

potential to dry out rapidly when a blast of air is applied, making its detection by electronic means difficult. This problem is compounded on the proximal surface where tooth separation and custom made wedges are necessary to gain electrical contact with the lesion (Longbottom and Pitts, 1993). Use of a technique without airflow in this region may bring about improvement, but moisture seeping from the gingival crevice may pose a problem.

8.2

Validation.

Various methods have been used to validate clinical diagnoses and these have been described in the literature review (page 31). Three methods have been used in this thesis; computer aided image analysis of macroradiographs prepared from tooth sections, visual inspection of serial sections and operative intervention *in vivo*. During cavity preparation in Chapter 6, softness of the dentine was assessed and soft dentine was shown to contain more bacteria than hard dentine. A recent study by Tveit *et al.* (1994), has assessed the softness of the dentine on histological section. Although this may differ once the tooth has been extracted, it is a relevant factor to take into account as it may correlate with bacterial infection *in vivo*.

All of the validation in this thesis was carried out by the author and it has been shown that the outcome of a caries diagnostic test may be influenced by both the validator and the validation technique (Wenzel *et al.*, 1994). This thesis has not investigated these influences as there was one validator and only three validation techniques, which were not compared. It is interesting to question whether the validation techniques used were

accurate enough to detect very small lesions? Consider the slightly lower specificity achieved with the ECM II in Chapter 5, compared with visual examination for dentine caries. This means that a number of apparently sound teeth (histologically) were recorded as carious by the ECM II. It is possible that the ECM II was more accurate than the histological technique and detected small lesions which the histological examination missed. A more accurate validation technique may therefore have produced a different result.

8.3 The accuracy of electronic caries diagnosis.

Using the validation techniques described in this thesis, a total of 176 molar and 52 premolar teeth have been investigated; 82 *in vivo*, 106 *in vitro* and 40 *in vivo* and *in vitro*. Multiple electronic readings were taken on some teeth and a total of 508 sites were investigated. Each experiment gave high sensitivity values for dentine caries diagnosis *in vitro* 93% (Chapter 2), 64% (Chapter 3), 92% (Chapter 4), 49% (Chapter 5 for molars) and 78% (Chapter 7). The lower results obtained in Chapter 5 can be explained by the small size of the lesions investigated and, in addition, the inexperience of the dentists in the technique may have been relevant. These results must be considered in the light of those obtained from visual and radiographic diagnosis in the same chapter (sensitivities of 19% and 23% respectively). The corresponding specificity values for the electronic diagnosis of dentine caries were 63% (Chapter 2), 100% (Chapter 3), 87% (Chapter 4), 82% (Chapter 5) and 85% (Chapter 7). The corresponding specificity values for visual and radiographic diagnoses determined in Chapter 5 were 99% and 83% respectively. These results are broadly in agreement with those previously published (Table 2.8, page

89) although some of the studies mentioned lack credibility alone because of the small number of teeth investigated (Sawada *et al.*, 1986; Verdonshot *et al.*, 1992).

8.4 Electronic techniques for the clinician and the epidemiologist.

Two techniques have been described, one which may be best suited to the clinician and the other optimal for the epidemiologist. Regardless of which technique is used surface conduction to the gingival margin has to be avoided because this would lead to false positive diagnoses. Surface conductance can be minimised in two ways and is the basis of the two different techniques which are described, that is site specific readings taken with an airflow and overall resistance readings taken with a contact medium and no airflow.

8.4.1 Site specific readings taken with an airflow.

Airflow used around a probe tip ensured that the area of contact with the tooth was standardised and helped to avoid false positive readings. Both the Vanguard electronic caries detector and the new ECM I and II prototypes had this facility. Quantification of the airflow showed it to be critical, and a flow of 7.5 l/min or greater was required to reduce false positive diagnoses. Two different scales were used with this technique; a conductance scale (the Vanguard and the ECM II) and a resistance scale (the ECM I and ECM II). Whilst this might have caused some confusion for the reader it seemed logical to simulate the conductance scale of the Vanguard in one prototype (ECM II) as well as investigating a newly devised cumulative resistance scale.

The term conductance has been used to describe the Vanguard scale and the ECM II stable conductance scale. Conductance however, is defined as $1/R$ (where R is the resistance) and Figure 4.3 A (page 127) shows that neither the Vanguard nor the ECM II scales conform to this formula. However, although these scales do not measure true conductance, with units of siemens, they do have a reciprocal relationship to resistance and the terms conductance and conductivity have been used synonymously in this thesis as meaning the ability to transmit electricity. No units have been given to the conductance scales for the Vanguard and the ECM II prototype to emphasise that they are not the same as true conductance.

Two different types of reading were recorded in Chapter 4 using the site specific airflow technique, that is stable conductance readings and cumulative resistance readings. The former recorded a conductance value when it had remained stable between the same two whole numbers for three consecutive seconds and the latter added the resistance values obtained at one second intervals so that an overall assessment of the drying out profile could be achieved. Although little difference was found between the accuracy of the cumulative resistance and the stable conductance readings, the poor reproducibility of the cumulative resistance readings precluded its further development. Reproducibility was poor, probably because the addition of resistance readings magnified any errors. In addition cumulative resistance readings have to be continued for at least 10 seconds for discrimination of dentine lesions and sound sites. This often took longer than obtaining a stable conductance measurement, and the quicker technique will obviously be preferred by dentists. Using this site specific technique a clinician can locate in a fissure the exact site at which the enamel is breached by caries, thus allowing the monitoring of small

lesions and, in cases where the entire fissure pattern looks the same, initial caries removal to be more discriminate.

8.4.2 Overall resistance readings taken with a contact medium and without airflow.

An epidemiologist may not be interested in such site specific information but may need accurate information about the maximum extent of a lesion on an occlusal surface. Surveys are often conducted remote from a dental surgery, without access to an air supply and thus it seemed logical to dispense with the air supply and use a contact medium along the entire fissure pattern after isolation with cotton wool rolls and tissue drying. It seemed possible that the probe could now be placed anywhere in the fissure system and a reading of the worst site obtained. However, the larger area of contact made the provision of a new scale mandatory because the larger area of contact led to lower resistance values. Results showed this technique could also produce accurate information about the caries status of a tooth (Chapter 7).

Although attention has been paid to the probe design and the clinical technique, the electrical circuit in this thesis was completed by a hand held connector. The resistance of the skin and body may reach 50 K Ω and this will depend upon the dryness and physical properties of the skin. However, in the lower resistance ranges these factors may affect readings and constitute a large error. Thus, when low resistances are to be measured, an oral electrode may provide a better electrical contact and reduce this error.

The accurate information obtained and the possibility of monitoring lesion progression,

arrest or remineralisation with objective measurements, makes this technique an interesting possibility for clinical trials, such as toothpaste trials. However, a National Survey conducted with such accuracy would give results in stark contrast to those which have been obtained in the past from visual examination alone and using cavitation as the diagnostic threshold. The question still remains, is this degree of accuracy required by the epidemiologist to determine future treatment needs of the population and changes in disease prevalence? Since it is suggested that fluoride may have changed the clinical presentation of the carious process, with cavitation occurring later, the further development of the ECM seems timely. However, do all detected lesions eventually proceed to require operative intervention?

8.5

Diagnosis and treatment.

Diagnosis should precede treatment. With our current knowledge of the carious process, treatment includes preventive management as well as operative intervention. Since preventive strategies, such as fissure sealing, are so effective on an occlusal surface, early diagnosis is very relevant to the contemporary practitioner.

8.5.1 The possible role of electronic diagnosis in disease monitoring.

Electronic caries detection can detect small enamel lesions, and performs well at the D₁ diagnostic threshold (Chapters 2,3,4,5,7). Enamel lesions in the walls of the fissure, like proximal lesions, have the potential for progression, arrest or even remineralisation and electronic diagnosis should offer the opportunity to monitor lesions with reproducible and objective measurements. However, the machine cannot be expected to discriminate

between mineral loss due to caries and hypomineralisation of developmental origin. Care must therefore be taken in interpreting the readings obtained on newly erupted teeth. Post-eruptive maturation should be demonstrated at subsequent recalls. A reasonable hypothesis might be that those patients whose resistance readings remain low over 18 months following eruption, may be regarded as caries-risk patients and early preventive measures such as fissure sealing would be appropriate. This hypothesis has yet to be tested.

8.5.2 The importance of reproducibility.

Electronic readings need to be reproducible if disease monitoring is to be effective. Changes in stable conductance readings taken at subsequent visits must reflect remineralisation or demineralisation changes within the tooth, not an error in taking a second reading. Similarly, reproducibility is essential if it is to be claimed that the disease process has not changed significantly when conductance readings have remained the same over a number of visits. Stable conductance readings taken with an airflow have been shown to demonstrate the reproducibility required, both within the same examiner (intra-examiner), and between examiners (inter-examiner). Thus good reproducibility, together with the strong relationships found between these readings and the mineral content in enamel and lesion depth, enables true disease monitoring to be performed objectively by clinicians.

Reproducibility is also important for the epidemiologist, both for National Surveys and trials of therapeutic agents. In National Surveys inter-examiner reproducibility is important, so that information can be collated and compared from different geographical regions. Differences will only be apparent between regions if the examiners and

examination aids are highly standardised and reproducible. Similarly true changes in caries prevalence can only be determined, when the surveys are repeated, if reproducibility is good. When clinical trials of therapeutic agents (eg toothpaste) are conducted, caries incidence is of paramount importance when the same population are re-examined. Thus, intra- and inter-examiner reproducibility are important so that the rate of caries progression is not confused with inconsistent data collection.

8.5.3 When to intervene operatively.

Dentine caries involvement would appear to be the most logical and clearly demarcated threshold upon which to base operative treatment. However, the results from Chapter 6 suggest that many shallow dentine lesions are hard to the probe and minimally infected with bacteria. The two layers of carious dentine described by Fusayama (1979) are important in this respect although *in vivo* work conducted in this thesis would appear to question whether the caries detector dye describes these layers correctly.

Fusayama (1979) showed demineralisation to proceed bacterial infection and only the latter requires operative treatment. Chapter 6 showed that the Vanguard would reliably diagnose demineralisation but could not differentiate infected and demineralised dentine from dentine that was demineralised but uninfected. Since the latter seems amenable to fissure sealing, operative treatment of all dentine lesions diagnosed by the Vanguard would constitute overtreatment. The clinician should use the bitewing radiograph since Chapter 6 showed that a radiolucency in dentine was the best predictor of infected dentine. However, the epidemiologist in the National Survey setting has no access to radiographs. Thus the epidemiologist still cannot predict different treatment needs using

electronic caries diagnosis. It is possible, however, that in future electronic diagnosis may provide more information on dentine caries. Chapter 4 has shown that with the new expanded stable conductance scale more information about lesion progression in dentine is available with the ECM II. Further work may show a relationship between electronic readings, appearance on bitewing radiograph and bacterial infection.

8.6 Recommendations for the final ECM.

For simplicity an epidemiologist in a National Survey requires caries present / caries not present data at a chosen diagnostic threshold such as dentine caries. This could be incorporated into a new machine by two coloured lights. The resistance cut-off levels which would illuminate each light could be chosen according to the diagnostic threshold required. Further work is required to show whether operative treatment needs can be assessed by selecting a cut-off level that coincides with visibility on radiograph and hence bacterial infection. A scale of lights comparable to the Caries Meter L indicating sound fissures, enamel caries only, shallow dentine caries only and dentine caries requiring treatment may not be practical, because the range of resistance values obtained for enamel lesions overlaps considerably with those obtained for sound sites and those for dentine lesions. Overlap is probably due to the great diversity of enamel lesions in their spacial extent and mineral content.

A simple two light system ignores the benefit of the ECM to the clinician, early lesion detection and monitoring. For this a continuous scale is required and it would seem appropriate to maintain the stable conductance scale. Thus the original idea of the

Vanguard with the smiling / frowning face and scale was correct, but expansion of the Vanguard scale into the continuous ECM II scale and regulation of the airflow has improved the original design of the Vanguard. The final ECM should consist of a scale allowing monitoring of lesion progression, a light which illuminates when operative treatment is required and a switch to convert from a scale suitable with airflow (and a means to regulate the flow) to one with a contact medium. These recommendations have been discussed with the physicist who produced the prototypes. The ECM is to be manufactured by a commercial company, *LODE*, Groningen, The Netherlands (Figure 8.1). The new ECM can be fitted to any dental unit, therefore, reducing the number of free standing instruments now used in modern practices. It is also possible that an electronic apex locator function, also based upon resistance changes, can be combined with the ECM II. Incorporation of these instruments into dental units may lead to appropriate and cost-effective treatment planning based upon objective measurements.

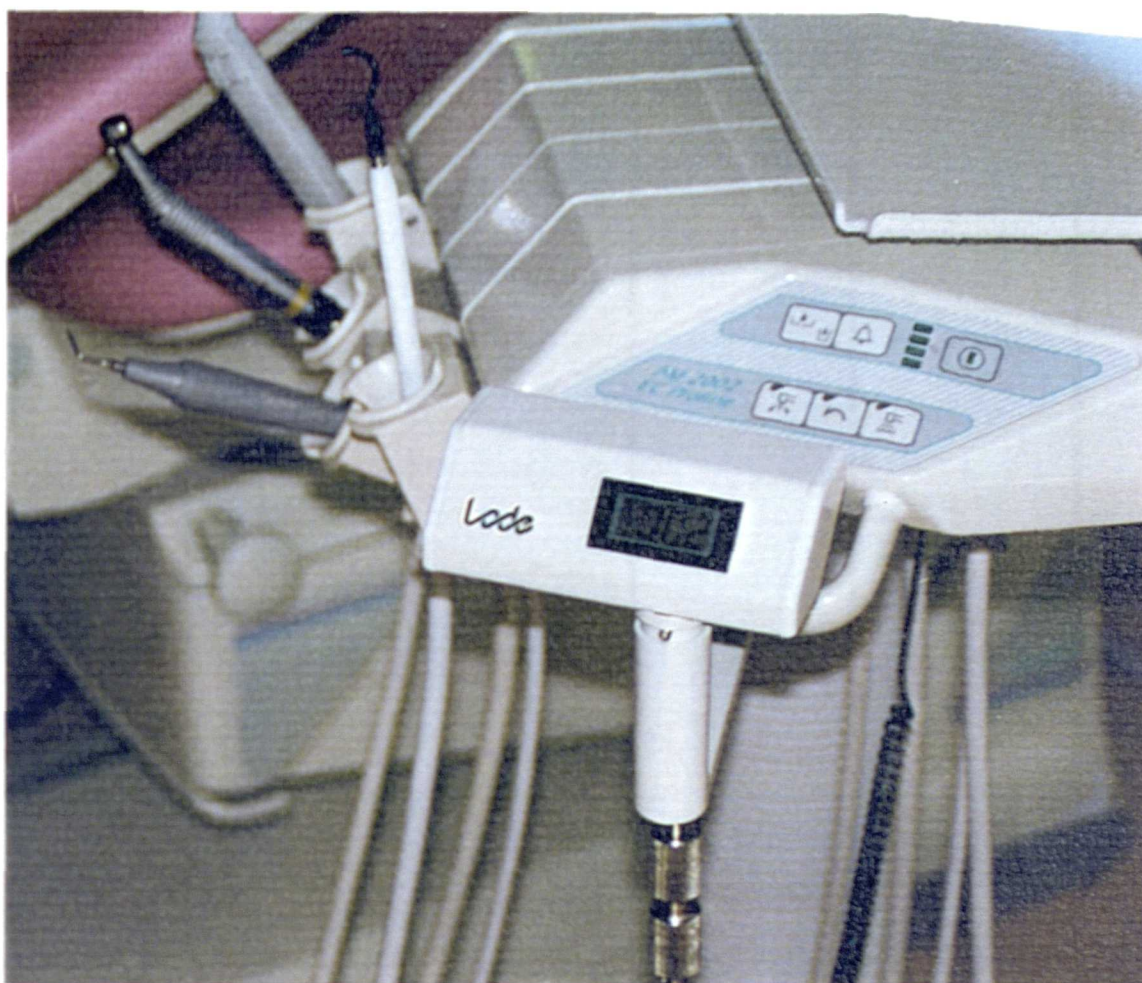


Figure 8.1 The new ECM manufactured by *LODE* and fitted to a dental unit.

The digital readout can be seen and the replaceable and autoclavable probe tip has it's own stand.

8.7

Further Work.

8.7.1 The development of overall resistance readings taken with a contact medium.

The development of resistance readings taken with a contact medium and no airflow is an interesting possibility, particularly for the epidemiologist, where an overall reading may be appropriate and access to an air source is not always possible. However, Chapter 7 of this thesis can only be considered a pilot study and further work is required. Histological validation of readings will be required and if this laboratory component is to have credibility, readings taken *in vitro* must be comparable to those taken *in vivo*. Thus, it will be important to determine initially whether resistance readings taken *in vivo* without an airflow and with a contact medium are comparable to those taken *in vitro* under the same conditions after extraction of the teeth. Laboratory work could subsequently be carried out to determine the relationship between stable resistance readings, taken in the lower resistance range without airflow and with a contact medium, and mineral content in enamel and lesion depth. The conductivity of various media should be investigated to determine whether different substances lead to significant changes in stable resistance values. It would be useful to compare stable resistance readings of teeth with and without radiolucencies on bitewing radiographs and determine whether a suitable cut-off reading can be used to differentiate between the two groups. Subsequently any correlation between stable resistance readings and bacterial infection could be assessed at operation using the clinical and microbiological techniques described in Chapter 6. If the cut-off reading was found to differentiate infected from uninfected dentine the method could be used to determine treatment needs in a National Survey and might reduce the

number of radiographs taken in the dental surgery.

8.7.2 Use of site specific ECM II readings taken with an airflow in dental practice.

This thesis has concentrated on site specific electronic readings taken with an airflow. However, the use of the ECM II on newly erupted teeth still needs investigation to determine whether these readings, taken prior to post-eruptive maturation, are different to those taken once the teeth have matured. Based upon these findings it may then be possible to determine the duration of post-eruptive maturation, by periodically repeating readings on newly erupted teeth until they reach that of the mature teeth. A longitudinal study on children may show whether it is possible to use the ECM II as a predictor of caries risk. A reasonable hypothesis to test might be that patients whose teeth give persistently high conductance/low resistance readings in the first 18 months following eruption are at risk to caries and may proceed to more fillings. The benefits and cost effectiveness of fissure sealing such patients' teeth should also be investigated.

8.7.3 Use of the ECM II in epidemiological surveys.

The use of the ECM II needs investigation by trained epidemiologists to determine whether its use in a National Survey setting is feasible, particularly with respect to inter-examiner reproducibility. Initial field work could be used to determine how many more dentine lesions could be detected with the ECM II compared to a standard visual examination. It is possible that disease prevalence, and therefore the treatment needs of the population, could be presented more accurately. The ECM II could also be used in long term clinical trials of preventive techniques, such as improved oral hygiene, or

therapeutic agents, such as toothpastes.

CHAPTER 9: GENERAL CONCLUSIONS.

The laboratory studies carried out in this thesis were mainly on third molar teeth, as these were the only non-cavitated molar teeth routinely extracted. These teeth may be morphologically different to other molars, and have a higher caries prevalence due to patients inability to maintain the occlusal surface plaque free. However, the readings taken on these teeth were comparable to those on other molar teeth investigated *in vivo* (Chapter 6) and were therefore thought to be relevant. It may also be argued that in some studies the sample sizes were small, however, they were comparable to many other studies published in refereed journals and even with such numbers many of the results were of statistical significance. Due to the difficulty in obtaining large numbers of suitable extracted teeth, multiple readings were taken on the same teeth. Therefore each reading may not be regarded as independent. However, the readings were objective and free from the subjective influence of other areas of the same tooth and the readings were thought by the author to be site specific due to the airflow. With these constraints in mind the answers to the research questions posed on page 66 are:

1. Electronic conductance readings taken *in vivo* were comparable to those taken in a laboratory set-up. This was determined for the Vanguard only and extrapolation to other ECMs is only an assumption. However, Vanguard readings taken *in vivo* were identical to those taken *in vitro* after extraction in 72 % of cases. Thus further laboratory work was justified.
2. Four electronic caries detectors have been investigated; the Vanguard caries detector, the Caries Meter L and the ECM I and ECM II prototypes. Each machine has been shown to have the potential to produce higher sensitivity values for occlusal dentine caries diagnosis (49-93%) than obtained for visual

examination, fibre optic transillumination or some types of radiographic examination. Specificity values were also acceptable (63-100%), but generally tended to be slightly lower than for visual and radiographic examination.

3. When an airflow is used around the probe tip, a minimum airflow of 7.5 l/min is required to reduce false positive diagnoses.
4. ECM II conductance readings have been shown to have a moderate to strong relationship with the mineral content in enamel and the depth of a lesion.
5. The technique of electronic caries detection needs little training to use; five untrained examiners achieved high sensitivity (mean = 63%) and specificity values (mean 87%) for diagnosis of occlusal caries in molar teeth at the D_1 diagnostic threshold, and good levels of intra-examiner reproducibility (mean percentage agreement 86%). Inter-examiner variation (coefficient of variation 7-9% for molars) was also shown to be lower, and therefore, better than obtained with other diagnostic techniques.
6. Use of a lower resistance scale without airflow and a contact medium spread on the entire fissure system enables an overall resistance reading to be taken, reflecting the site where the carious process is most advanced.
7. The recommendations in this thesis have led to the development of a new ECM which can be fitted to dental units, and is now to be manufactured, supplied and fitted by *LODE*, Groningen, The Netherlands. This modified device needs further evaluation with respect to: readings on premolar teeth; readings taken with a contact medium and no airflow; the potential for use in an epidemiological survey; its use in practice by general practitioners in the assessment of caries risk and how this may alter a practice work profile.

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Appendix I A summary of optimum sensitivity and specificity values, respective cut-off values and the area under the ROC curves for different types of readings at the D_1 diagnostic threshold.

	Type of Reading	Air Flow l/min	Optimum Sens %	Optimum Spec %	Cut-off	Sens at Spec 93 %	Cut-off	Area under ROC curve
Stable conductance		5	82	67	4.43	25	12.45	0.76
		7.5	61	96	1.74	61	1	0.8
		1	71	78	0.23	59	2.55	0.83
2 seconds		5	74	70	0.30 MOhms	31	0.16 MOhms	0.76
		7.5	76	89	1.9	63	1.45	0.9
		10	76	85	5.4	65	3.5	0.92
4 seconds		5	71	67	1.15	29	0.38	0.78
		7.5	71	89	10.5	67	10.4	0.89
		1	78	82	30.5	65	12.2	0.92
6 seconds		5	80	63	4.75	25	0.63	0.78
		7.5	84	74	67.1	61	20.4	0.87
		1	76	82	67.9	55	24.1	0.89
8 seconds		5	81	67	9.94	29	1.12	0.79
		7.5	76	78	109	55	32.8	0.86
		1	74	85	114	59	43.7	0.89
10 seconds		7.5	86	67	209.5	55	51.6	0.86
		10	74	85	154	59	60.7	0.89
12 seconds		7.5	86	67	289.5	55	77.6	0.85
		10	69	89	189.05	61	83.7	0.88
14 seconds		7.5	86	67	369.5	55	113.6	0.87
		10	74	82	269.05	61	128.7	0.88
15 seconds		7.5	86	67	409.5	59	153.6	0.87
		10	74	82	309.05	63	168.7	0.87

Appendix II A summary of optimum sensitivity and specificity values, respective cut-off values and the area under the ROC curves for different types of readings at the D_2 diagnostic threshold.

	Type of Reading	Air Flow l/min	Optimum		Cut-off	Sens at Spec 93%/%	Cut-off	Area under ROC curve
			Sens/%	Spec/%				
Stable conductance		5	87	60	4.43	10	12.74	0.75
		7.5	74	95	1.74	74	1.74	0.86
		1	80	92	1.29	74	2.55	0.89
Cumulative resistance after	2 seconds	5	65	80	0.30 MOhms	39	0.16 MOhms	0.79
		7.5	85	81	1.9	8	0.21	0.89
		10	77	92	3.3	69	1.65	0.92
	4 seconds	5	85	70	1.15	31	0.37	0.82
		7.5	72	89	8.7	54	2.9	0.87
		1	80	95	12.2	80	12.2	0.94
	6 seconds	5	74	70	1.9	26	0.57	0.82
		7.5	69	92	17	59	13.3	0.88
		1	87	87	65	67	21.05	0.95
	8 seconds	5	72	73	2.85	28	0.87	0.82
		7.5	72	84	59.82	62	29.9	0.89
		1	87	87	112.6	74	43.7	0.94
	10 seconds	7.5	72	87	93.25	64	46.2	0.89
		10	87	87	152.6	74	60.7	0.93
		7.5	69	95	77.6	69	77.6	0.9
	12 seconds	10	85	89	189.05	77	83.7	0.94
		7.5	72	92	129.9	69	113.6	0.92
		10	85	89	237	77	128.7	0.94
	15 seconds	7.5	72	95	147.9	72	147.9	0.91
		10	85	89	260	80	168.7	0.94

Appendix III A summary of optimum sensitivity and specificity values, respective cut-off values and the area under the ROC curves for different types of readings at the D₁ diagnostic threshold.

	Type of Reading	Air Flow l/min	Optimum Sens/%	Optimum Spec/%	Cut-off	Sens at Spec 93%/%	Cut-off	Area under ROC curve
Stable conductance		5	79	64	11.23	13	12.69	0.77
		7.5	92	87	2.24	58	5.28	0.89
		10	92	89	2.27	79	4.18	0.92
Cumulative resistance after	2 seconds	5	79	69	0.24 MOhms	17	0.10 MOhms	0.83
		7.5	83	75	1.45	46	0.33	0.89
		10	83	87	1.6	42	0.55	0.94
	4 seconds	5	83	67	0.75	17	0.26	0.82
		7.5	88	81	5.7	42	1.1	0.88
		10	88	83	10.7	71	4.35	0.95
	6 seconds	5	79	64	1.52	33	0.57	0.82
		7.5	83	83	16.7	50	4.5	0.9
		10	88	90	21.05	75	13.4	0.96
	8 seconds	5	79	64	2.85	33	0.8	0.82
		7.5	88	79	46.25	50	7.5	0.91
		10	92	87	41.7	75	19	0.98
	10 seconds	7.5	88	81	62.9	50	9.9	0.92
		10	96	87	96.87	75	24.8	0.97
	12 seconds	7.5	88	85	77.6	54	14.3	0.93
		10	92	87	77.1	71	31	0.96
	14 seconds	7.5	88	85	113.6	63	33.34	0.95
		10	92	89	78.1	67	37.5	0.97
	15 seconds	7.5	88	85	125.3	63	37.14	0.95
		10	92	89	85.7	63	40.9	0.97

Appendix IV The relationship between reading type (demonstrated by Spearman correlation coefficients) and the percentage mineral content in enamel and depth of the lesion measured from the surface of the tooth, for the whole sample and enamel lesions only. The relationship between readings and the percentage mineral content in dentine and the depth of lesion measured from the EDJ are also shown for dentine lesions only.

Spearman correlation coefficients								
Reading Type	Air flow l/min	Whole sample		Enamel lesions only		Dentine lesions only		
		% mineral in enamel	Lesion depth from surface	% mineral in enamel	Lesion depth from surface	% mineral in dentine	Depth of lesion from EDJ	
Cumulative resistance after	Stable	7.5	-0.67**	0.64**	-0.45*	0.24	-0.46*	0.53**
	conductance	1	-0.68**	0.66**	-0.41	0.18	-0.4	0.54**
	2 seconds	7.5	0.69**	-0.71**	0.07	0.08	0.60**	-0.64**
		1	0.75**	-0.73**	0.36	-0.01	0.56**	-0.68**
	4 seconds	7.5	0.68**	-0.70**	0.1	-0.06	0.61**	-0.53**
		1	0.80**	-0.75**	0.50**	-0.16	0.46*	-0.59**
	6 seconds	7.5	0.71**	-0.71**	0.27	-0.08	0.58**	-0.57**
		10	0.78**	-0.74**	0.53**	-0.23	0.43*	-0.56**
	8 seconds	7.5	0.71**	-0.70**	0.36	-0.17	0.50*	-0.54**
		10	0.78**	-0.74**	0.60**	-0.27	0.42*	-0.54**
	10 seconds	7.5	0.71**	-0.70**	0.35	-0.21	0.49*	-0.52**
		10	0.77**	-0.73**	0.58**	-0.26	0.39	-0.50**
	12 seconds	7.5	0.71**	-0.71**	0.37	-0.25	0.46*	-0.50**
		10	0.77**	-0.73**	0.54**	-0.23	0.39	-0.48*
	14 seconds	7.5	0.71**	-0.71**	0.37	-0.26	0.46*	-0.50**
		10	0.76**	-0.72**	0.53**	-0.23	0.38	-0.47*
	15 seconds	7.5	0.71**	-0.71**	0.37	-0.26	0.44*	-0.49**
		10	0.76**	-0.72**	0.52**	-0.24	0.40*	-0.50**
		** P LE 0.01		* P LE 0.05				